

EXHIBIT 18

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

**BEFORE THE HONORABLE JOAN N. ERICKSEN
UNITED STATES DISTRICT COURT JUDGE**

APPEARANCES

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Wiley, 2010, 10.1002/rsa

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10 C O U R T R E P O R T E R S : M A R I A V . W E I N B E C K , R M R - F C R R
11 R E N E E R O G G E , R M R , C R R
12 1005 U.S. Courthouse
300 South Fourth Street
12 Minneapolis, Minnesota 55415

14 Proceedings recorded by mechanical
15 stenography; transcript produced by computer.

PROCEEDINGS

2 (9:03 a.m.)

(Jury in.)

4 THE COURT: Good morning, everybody. Go ahead and
5 be seated. Members of the jury, you can sit now wherever
6 you went. I was so firm yesterday about how you had to sit
7 in a particular seat, and we no longer care. I understand
8 that some judges make jurors sit in the same seat all
9 through trial, but I think what if you want to change?

10 Please be seated everybody. What if you want to change or
11 what if you decide you can't hear or see or you get sick of
12 your neighbor or anything like that. So from now on, you
13 have that limited amount, you have that limited amount of
14 freedom.

15 And as I told you yesterday, we're going to start
16 with the opening statements of the lawyers. Remember that
17 the opening statements have the purpose of previewing for
18 you what the lawyers think the evidence is going to be. The
19 statements themselves are not evidence. Let me just ask the
20 lawyers if they're ready. Ms. Zimmerman, are you ready?

MS. ZIMMERMAN: Yes, Your Honor.

THE COURT: And over here, Mr. Blackwell?

MR. BLACKWELL: Yes, Your Honor.

THE COURT: And the plaintiff being the party with
the burden goes first. Ms. Zimmerman, we are ready to hear

1 from you.

MS. ZIMMERMAN: Thank you, Your Honor.

3
4 OPENING STATEMENT BY MS. ZIMMERMAN
5 May it please the Court, counsel, Mr. And Mrs.
6 Gareis's, and Ladies and Gentlemen of the Jury:
7 My name is Genevieve Zimmerman, and I'm one of the
8 plaintiff's lawyers who gets to represent these fine folks.
9 And as the Judge has instructed you, I get to provide you a

10 little bit of a road map about what we expect the evidence
11 is going to show during this trial.
12 A couple of signs that I would suggest will help
13 guide your receipt of this evidence. Listen carefully for
14 risk and utility. The risk of using the Bair Hugger in an
15 orthopedic surgery. Listen to hear if you have presented to
16 you any evidence about utility, benefit of using the Bair

18 So what is the Bair Hugger? You've been waiting
19 all day yesterday and now today to hear a little bit more
20 about it. The Bair Hugger is a patient warming device.
21 There is actually one of them right here. This is the
22 exact -- not the exact model that was used in Mr. Gareis's
23 surgery. It's a Model 505. One like this was used in
24 Mr. Gareis's surgery.

	173		175
1 periprosthetic joint infections, correct?		1 numbers -- allows or deposits a small number of particles	
2 MR. BLACKWELL: Objection, Your Honor, Rule 402.		2 over the surgical site, is that okay?	
3 THE COURT: Sustained.		3 A. Only if there's a risk of increasing the infection rate.	
4 BY MR. CIRESI:		4 Q. Well, you know that it could increase -- it could cause	
5 Q. Well, you evaluated, did you not, the risk of using the		5 infection if that got into the surgical site, correct?	
6 Bair Hugger for prosthetic joint surgery?		6 A. It's possible.	
7 A. Well, I certainly participated in a number of hazard		7 Q. So how many bacteria should it allow to get there?	
8 analyses over the years.		8 Where is the cutoff if you're going to use this device in	
9 Q. And you would agree that the Bair Hugger should not		9 orthopedic surgery?	
10 increase the particle count over the surgical site?		10 A. Well, again, I don't think that would be the standard by	
11 A. I'm not sure what you, as part of a hazard analysis or?		11 which it's judged. We'd want to look at the outcomes	
12 Q. In this actual operation for periprosthetic joint		12 associated with its use, not necessarily particles of	
13 surgery, should it increase particulate count over the		13 bacteria, since no one knows what the threshold is.	
14 surgical site in its intended use?		14 Q. And that study has never been conducted by 3M, has it?	
15 A. Well, I think the hazard that we would look at would be		15 A. Well, we've looked at -- we've looked at the use of	
16 the risk of infection not the number of particles.		16 forced air warming in a variety of surgical settings to look	
17 Q. Well, you understand that very small number of particles		17 at the reduction of risk in infections.	
18 could cause an infection?		18 Q. Sir, has the study ever been conducted by 3M to see how	
19 A. Depending on size, yes.		19 many particles should be allowed to go through this tube	
20 Q. Okay. Now, then all I want to know is is it part of its		20 into this blanket putting out air, disrupting the airflow	
21 intended use that it should increase the number of particles		21 and possibly depositing over the surgical site, has that	
22 over the surgical site? Is that one of its intended		22 study ever been conducted by 3M?	
23 purposes?		23 MR. BLACKWELL: Objection, Your Honor, 402 and	
24 A. No.		24 701.	
25 Q. It shouldn't do that, should it?		25 THE COURT: Well, if you're able to answer that	
	174		176
1 A. Well, it's not part of its intended use.		1 question, go ahead and do so.	
2 Q. And it should not do it, isn't that right?		2 THE WITNESS: Well, there were a lot of parts.	
3 A. Well, we certainly want to minimize that.		3 I'm not sure which --	
4 Q. So it's okay if a few show up over the site; is that		4 MR. CIRESI: That's fair.	
5 right?		5 BY MR. CIRESI:	
6 A. Well, again, the risk of that is a question that we		6 Q. Have you ever done or --	
7 would evaluate.		7 THE COURT: Make sure that you remember to use the	
8 Q. But is it okay if a few show up over the site as a		8 microphone, Mr. Ciresi.	
9 result of its use?		9 BY MR. CIRESI:	
10 A. Well, it depends on whether a small number has an effect		10 Q. Have you ever, and by "you" I mean the company, ever	
11 on an outcome like infection.		11 conducted a study to determine how many particles over the	
12 Q. Well, you know it does based on the literature, don't		12 surgical site would result in a prosthetic joint infection?	
13 you?		13 A. No.	
14 A. Again, that is not a settled question. The relationship		14 Q. But it's my understanding that your testimony is that	
15 between particulates and bacteria is not well-established.		15 you know that a certain number of particles are going to get	
16 Q. So you don't know whether it's one or two or a hundred?		16 over the surgical site?	
17 A. Well, nor does anyone else.		17 THE COURT: Okay, I think we've covered this.	
18 Q. But you do know that there's a substantial body of		18 Let's go on to something else.	
19 scientific people who believe that a very small number		19 BY MR. CIRESI:	
20 including Mr. Hansen can cause a joint infection? You know		20 Q. Would you agree with me that there was no reason to	
21 that, don't you?		21 increase particle loads over the surgical site from a safety	
22 A. Yes, I believe that people do believe that a small		22 standpoint?	
23 number of bacteria or particles can cause an infection, yes.		23 A. I can't think of a reason why that would be beneficial.	
24 Q. So I'm back to where I was, and that is is it okay then		24 Q. In fact, it would be unreasonable to do that, wouldn't	
25 if the normal operation of this device deposits small		25 it?	

	177		179
1 A. Well, intentionally, yes.		1 A. Again, I would have to see the results of that study to	
2 Q. Because that would create potentially an unsafe		2 comment on it. That was some time ago.	
3 condition, correct?		3 Q. All right. Could you go to your deposition, sir?	
4 A. Potentially.		4 A. And where is that?	
5 Q. And if a small number of bacteria can cause an infection		5 Q. It should be right there.	
6 in a prosthetic joint replacement, that could cause		6 MR. CIRESI: May I approach, Your Honor?	
7 catastrophic injury, can't it?		7 THE COURT: You may. Give it to the witness,	
8 A. It could.		8 please.	
9 Q. Now, you would agree that every study shows that the		9 MR. CIRESI: I have one for, Your Honor.	
10 Bair Hugger increases the absolute count of particles over		10 THE COURT: Okay. Patrick, would you take it?	
11 the sterile field; correct?		11 BY MR. CIRESI:	
12 A. As far as I know, in absolute numbers the particulate		12 Q. Could you go to page 170, 171, sir? And just to refresh	
13 count goes up in a trivial amount, yes.		13 your recollection, starting at the bottom of 170, line 18,	
14 Q. And there's no internal studies that you're aware of to		14 over to 171, line 3. Then I'll ask you a question. Are you	
15 refute that, correct?		15 looking at the March 7th deposition, sir?	
16 A. That they're refuted?		16 A. This one is from yes, March 7th, yes, got it.	
17 Q. That would refute that?		17 Q. Have you read it?	
18 A. None that I'm aware of.		18 A. So there's a mention of Schlieren imaging there, yes.	
19 Q. Okay. And did you participate in a Schlieren imaging		19 Q. And the question was, question at line 18, 170:	
20 study at 3M?		20 "You would agree with me there was an effect on	
21 A. Well, I have been present for a number of Schlieren		21 the imaging is what I'm thinking about that I've seen that	
22 activities. I'm not sure they were studies, but I have,		22 was produced, there was an effect on the unidirectional	
23 yes.		23 airflow by the Bair Hugger blanket?"	
24 Q. Okay. And you were present at one that was done in 2010		24 A. I'm sorry, where was that again?	
25 or '11, correct?		25 Q. Page 170, line 18.	
	178		180
1 A. It's possible. I would have to look at any if we made a		1 A. Are you talking about the number on the page or the	
2 report or.		2 number on the deposition pages?	
3 Q. Do you recall being asked about this in your deposition,		3 Q. Deposition page 170, sir.	
4 sir?		4 A. So mine starts with page 18, oh, okay, got it. I see it	
5 A. Yes, I recall being asked about Schlieren Photography.		5 now.	
6 Q. Okay. And there are images that you get off of		6 Q. Deposition page 170, line 18 on the deposition page.	
7 Schlieren Photography, correct?		7 Are you there, sir?	
8 A. Yes.		8 A. I'm there.	
9 Q. And the purpose of a Schlieren is to look at the effect		9 Q. Okay.	
10 of the temperature various blankets would have on the		10 "Question: You would agree with me that there was	
11 airflow in a laminar airflow setting. That was the purpose		11 an effect on the imaging if it's the one I'm thinking about	
12 of the study or test, I should say.		12 that I've seen that was produced. There was an effect on	
13 A. Well, I think that might have been one of the purposes,		13 the unidirectional airflow by the Bair Hugger blanket?	
14 yes.		14 Answer: In the test fixture that we put up, yes.	
15 Q. And that was an experimental study, correct, or test?		15 Question: There was an effect on the	
16 A. I'm not sure exactly what you mean by an experimental		16 unidirectional airflow, correct?	
17 test.		17 Answer: Yes."	
18 Q. Well, it didn't replicate an actual operating room, did		18 Did you give those answers at that time?	
19 it?		19 A. Yes.	
20 A. No, no.		20 Q. Then you recall that study, sir?	
21 Q. It was a test, fixture, correct?		21 A. Yes, I recall that activity, yes.	
22 A. That's right, in a laboratory.		22 THE COURT: Just hold on one second.	
23 Q. And in the one that you participated in, the imaging		23 THE WITNESS: Page 170, yes, line 18.	
24 showed an effect on the unidirectional airflow by the Bair		24 THE COURT: Mr. Ciresi, would you approach,	
25 Hugger blanket, didn't it?		25 please?	

	181		183
1	MR. CIRESI: Pardon me, Your Honor?	1	DIRECT EXAMINATION
2	THE COURT: Would you approach, please?	2	BY MR. BLACKWELL:
3	(Sidebar conference.)	3	Q. Good afternoon, Mr. Van Duren.
4	THE COURT: This is -- it's not going to say that	4	A. Good afternoon.
5	at all.	5	Q. We're back to discussing particles and bacteria again.
6	MR. CIRESI: Oh, my god, it's the March 7th. I'm	6	For the ladies and gentlemen of the jury, are particles and
7	sorry, yeah.	7	bacteria the same thing?
8	(IN OPEN COURT)	8	A. No.
9	BY MR. CIRESI:	9	Q. Why not?
10	Q. So you gave those answers to that question, correct,	10	A. Bacteria have a certain size that's generally bigger
11	sir?	11	than many of the particles that in the operating rooms, so
12	A. Yes, those are my answers, yes.	12	particles, many particles that are in the air are not big
13	Q. Now, in evaluating the risk benefit of the Bair Hugger,	13	enough to have bacteria on them.
14	to your knowledge up through 2011, were any studies done to	14	Q. Do particles in of and by themselves cause surgical site
15	determine if the Bair Hugger caused surgical site	15	infections, just particles?
16	infections?	16	A. No, bacteria cause infections.
17	A. Well, there were a number of --	17	Q. And would all particles necessarily contain bacteria
18	Q. I'm asking if the company, sir.	18	just because they're in the room?
19	A. If the company had done any to --	19	A. No, many of them don't contain any bacteria.
20	Q. Yes?	20	Q. Is there a certain size particle capable of even housing
21	A. Internal microbiology studies? Is that what you're	21	or containing a bacteria?
22	asking? I want to make sure I answer your question.	22	A. Yes. It generally has to be, generally has to be above
23	Q. Any testing to determine if the Bair Hugger causes	23	two microns to have bacteria on it.
24	surgical site infection?	24	Q. A particle has to be above two microns to have bacteria
25	A. Well, we had commissioned studies to look at the effect	25	on it?
	182		184
1	of the use of the Bair Hugger in surgeries to see if they	1	A. Yes.
2	increased the risk of surgical infections, yes.	2	Q. Do you have any basis or foundation to know what size
3	Q. So your answer is yes, it has?	3	particles were in the operating room as pertains to
4	A. Yes.	4	Mr. Gareis?
5	Q. Could you go to the same deposition, page 183?	5	A. No, I don't.
6	MR. BLACKWELL: Page what?	6	Q. You had a lot of discussion about core temperatures,
7	MR. CIRESI: 183.	7	35.5 degrees or celsius or less, do you remember that
8	THE WITNESS: Yes, I'm there.	8	discussion?
9	BY MR. CIRESI:	9	A. Yes.
10	Q. Okay, 183, did you give the following answer to the	10	Q. Do you have any basis or foundation to know what was the
11	following question at line 4?	11	core body temperature of Mr. Gareis?
12	"Question: Okay, with respect to the Bair Hugger	12	A. No, I have not reviewed any records of that case.
13	Patient Warming System causing surgical site infection, was	13	MR. BLACKWELL: Your Honor, we're going to ask
14	there any internal testing done by the company 3M, Arizant	14	Mr. Van Duren to come back in our case, so we'll stop there.
15	or Augustine Biomedical with respect to that?	15	THE COURT: All right. You are free to step down.
16	Answer: And what was the outcome?	16	MR. CIRESI: Your Honor, I have a couple
17	Question: Surgical site infection.	17	questions.
18	Answer: No."	18	THE COURT: Do you have anything just based on
19	Did you give those answers on that date?	19	what the couple questions we just heard?
20	A. I did give those answers.	20	MR. CIRESI: Yes.
21	MR. CIRESI: Thank you. I have no further	21	THE COURT: Very briefly, Mr. Ciresi. You may
22	questions.	22	proceed.
23	THE COURT: Okay. Mr. Blackwell, any questions?	23	RECROSS EXAMINATION
24	MR. BLACKWELL: I'll be very brief, Your Honor.	24	BY MR. CIRESI:
25	THE COURT: Okay.	25	Q. Particles I want to talk to you about just a second.

1 UNITED STATES DISTRICT COURT
 2 DISTRICT OF MINNESOTA
 3 -----
 4)
 5 Louis Gareis and Lillian) **VOLUME II**
 Gareis,)
 6 Plaintiff,) File No. 16-CV-4187
 v.) (JNE/FLN)
 7 3M Company and Arizant) May 16, 2018
 Healthcare, Inc.,) Minneapolis, Minnesota
 8 Defendant.) Courtroom 12W
 9) 9:11 a.m.
 10)
 11 -----
 12 BEFORE THE HONORABLE JOAN N. ERICKSEN
 UNITED STATES DISTRICT COURT JUDGE
 13 (JURY TRIAL - VOLUME II)
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1 **P R O C E E D I N G S**
 2 (9:11 a.m.)
 3 **(In open court with the jury present)**
 4 THE COURT: Good morning. Please be seated
 5 everybody. Welcome back.
 6 Please be seated. And, Ms. Conlin, we are in the
 7 middle of Dr. Presnal's middle or somewhere.
 8 MS. CONLIN: Yep, we're going to recall to the
 9 stand by way of video deposition Dr. Presnal. Your Honor,
 10 we played part of it yesterday. We're picking up at
 11 page 27, line 1.
 12 THE COURT: Thank you.
 13 **(Video deposition of Dr. Bradley Presnal played as follows)**
 14 Q. Now, unfortunately, Mr. Gareis developed an infection
 15 after this, correct?
 16 A. Yes.
 17 Q. Do you know what type of infection it was?
 18 A. Let me see if I can find it here. So when I saw him in
 19 August of 2011, he came back in with some pain so he did
 20 a --
 21 Q. What page are you on, sir? There should be a number
 22 down at the bottom there?
 23 A. 25,000. So I had actually seen him before that because
 24 he came back in said his hip was starting to bother him.
 25 That was July of 2011, and he came back in because his hip
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1 had done well initially but then started having some pain
 2 and so we sent him in for some blood work, a CRP,
 3 C-reactive protein and a sedimentation rate.
 4 Q. What does that tell you?
 5 A. So those are inflammatory markers, generally if they're
 6 elevated, if both are elevated that can be a sign of
 7 infection so that's when we use two because one alone may
 8 not be very indicative of an infection. I was trying to see
 9 if we had those results. I have in my note both the CRP and
 10 sed rate were elevated which can be an indication of
 11 infection, and so we did an aspiration. We drew fluid off
 12 his hip to check for infection. It came back with a
 13 coag-negative staph.
 14 Q. What kind of organism is that?
 15 A. So it's kind of a slow growing organism. It typically
 16 doesn't make people very ill. You know, high fevers, night
 17 sweats, things like that. Generally, just creates pain at
 18 some point. It's a hard one to diagnose sometimes because
 19 it's hard to grow in the lab. Sometimes you can get, you
 20 know, inconsistent cultures with it. And sometimes the only
 21 thing it causes is pain. People don't have any other
 22 symptom you would expect with an infection.
 23 Q. Was his symptomology consistent with that type of
 24 infection?
 25 A. I think so where he comes in, he's not feeling bad, just
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1 A. Well, that's an area of debate, but decades of --
 2 research dating back decades have even said as many as one
 3 bacteria. But it's just probably several.

4 Q. Okay.

5 A. Just a few.

6 Q. Just a few?

7 A. Just a few. But very respective researchers have said
 8 one.

9 Q. You used the term "ultra-clean." Can you define what
 10 that means.

11 A. When you package an implant, it is truly sterile. It's
 12 packaged in a factory in a clean room where there's no
 13 bacteria, and that's sterile. That's the true definition of
 14 sterility, where there's no viable organism. A bacteria is
 15 an organism. And when you take that component out of the
 16 package to put it into the patient, it's now in the air.

17 Unfortunately, even though this looks clean in
 18 here, the room and air looks clean -- you can't see clouds
 19 or smoke -- there is all this microscopic stuff going on in
 20 the air right now. And it will then no longer then be 100
 21 percent sterile. It's going to be ultra-clean. That is it
 22 might have bacteria on it. It might not have bacteria on.
 23 Any time there is a chance it might have bacteria on it,
 24 then it's what we call ultra-clean.

25 We try to make the -- we try to make the room as

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 1 sterile as we can, but we never can get to a one hundred
 2 percent sterility. The good news is we know that if we keep
 3 that level of bacteria down to a certain amount, then the
 4 chance of you not having infections is really low.

5 THE COURT: Meaning you have an infection?

6 THE WITNESS: Chance of you having an infection,
 7 yes, Your Honor. It's really low if you can keep that down.
 8 So you have to control the environment and make it an
 9 ultra-clean environment.

10 It's one of the reason why when I open these
 11 components, I only open them the minute I need them. So I
 12 believe I'm actually putting a sterile component in because
 13 I'm not letting the environment see this component for very
 14 long. So that's one way I control the environment, is just
 15 open it when I need it. Everybody on my team knows that,
 16 and that's standard of care.

17 BY MR. FARRAR:

18 Q. Are there, those components, are they -- tell me how
 19 they are packaged.

20 A. They're packaged many different ways, but they are often
 21 three layers. So there is a package within a package within
 22 a package. And the exact mechanics of how the factory does
 23 it, I'm not an expert in that, but it's done in a clean room
 24 basically where it's free of bacteria and organisms.

25 Q. If there are bacteria organisms above the open incision,

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1 can they attach to the prosthesis?
 2 A. Surely. One thing to think about is every room has
 3 bacteria, skin cells. Humans shed up to 10 to the 9th. I
 4 think that's about 100 billion skin cells a day. So it's an
 5 amazing number that humans shed of their skin.
 6 Skin cells also have bacteria. There's also
 7 particles that have bacteria on them. And there is lint and
 8 dust that have bacteria on it. This is all floating in the
 9 air right in here. It's kind of gross to think about. But
 10 there's plenty of studies that date back many decades and
 11 even recently -- one I saw in 2012, a study that showed that
 12 the floors are full of skin, and dust, and bacteria. What
 13 happens is it's in the air and then it settles on the floor.
 14 And that happens when people walk into a room.

15 So I imagine this room is cleaned every day, and
 16 most rooms in public-use buildings are cleaned every day.
 17 And if we were to study this room before all of us came in
 18 here, we would find a whole lot less microbiological load in
 19 here, meaning a lot less skin cells, a lot less bacteria, a
 20 lot less dust, particles. A lot of its on the floor. Some
 21 of it's floating in the air -- a lot of it's floating in the
 22 air. But when we all came in here -- no offense taken, Your
 23 Honor, including Your Honor --

24 THE COURT: Leave me out of this.

25 THE WITNESS: Okay, I will. And me, the officers
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 1 of the court, y'all, the spectators, we just brought in
 2 trillions of stuff into this room. It's really gross to
 3 think about, but that's what we did. And all of that has
 4 potential bacteria.

5 You can't make an operating room a clean room.
 6 Maybe one day in the future, space, in 2200 or 2300 or
 7 something like that we might have a clean room we can
 8 operate in, and that will be a happy day. Right now we
 9 can't do that.

10 So as soon as all of us walk into the room and we
 11 bring in all of our stuff, we have to have a way to protect
 12 the patient. That's what ultra-clean is all about, is
 13 trying to protect the patient from having all the stuff --
 14 bacteria, skin cells, particles, lint, dust -- that just is
 15 naturally on you and falls off you get into the wound. The
 16 way we do that is through a lot of different mechanisms. I
 17 don't know if you want me to go into it.

18 BY MR. FARRAR:

19 Q. No, I do. I want to talk about what you as an
 20 orthopedic surgeon -- what orthopedic surgeons in general do
 21 to protect the patients from surgeries. I want to start
 22 with the ventilation system if we would.

23 If you could put up 1606.

24 So, Doctor, I'm showing -- this is, obviously, not
 25 to model Mr. Gareis' operating room, sort of a generic

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1 operating room, but I want to talk about the ventilation.
 2 Describe to me what unidirectional flow is and how it
 3 protects the patient from infection risks.
 4 **A. This is what I'm talking about. When we walk into a**
 5 **room, we bring a bunch of our stuff with us. What I tell my**
 6 **team every day and they say, Yeah, Doc, we know, bacteria is**
 7 **your number one enemy. Well, it is. It's my number one**
 8 **enemy because it's my patient's number one enemy.**

9 **The way we do it is create a unidirectional --**
 10 **protect the patient is create a force field is that you can**
 11 **see -- can I draw on this?**

12 Q. Yep.

13 A. **This is -- up here are the diffusion panels where air is**
 14 **being -- clean air is being pushed through into the**
 15 **operating room. And it pushes those falling skin cells, and**
 16 **lint, and dust, and everything that we don't like on our**
 17 **patients down and out, so away. It's basically creating**
 18 **this force field that the patient is in, and all that stuff**
 19 **is being exhausted to the returns or the exhaust fans in the**
 20 **room.**

21 **So clean air coming down. How we get that clean**
 22 **air? We do it through filtered air. We have a filter that**
 23 **is often a HEPA filter and close to one hundred percent**
 24 **filtration -- never one hundred percent because we're**
 25 **humans; I think it's 99.97 percent filtering out at a**

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1 **certain size of particle. And not just that filter, that**
 2 **filter will be right here before the diffusion panels, but**
 3 **there's another one downstream from it and then another one**
 4 **often downstream from that. Sometimes an ultraviolet light**
 5 **is thrown into the mix where it's also killing bacteria. So**
 6 **you have filter, ultraviolet light, filter, filter, air**
 7 **coming into the operating room. We're doing the best**
 8 **humanly possible. It's not the best we will have one day,**
 9 **but it's the best right now.**

10 Q. The ultraviolet light, does it eradicate particles or
 11 bacteria?

12 A. **The ultraviolet light will kill bacteria on particles.**

13 Q. So the bacteria are riding on the particles?

14 A. **That's right.**

15 Q. I'm sorry, I didn't mean to interrupt you.

16 A. **So it's pushed down, and then that's called**
 17 **unidirectional flow. And then it's pushed out the exhaust**
 18 **fans.**

19 **And I think it's very important, that dates back**
 20 **to Sir John Charnley. He was knighted for his work in**
 21 **orthopedic surgery. He's an amazing man. He's a man that**
 22 **most orthopedic surgeons revere because he came up with this**
 23 **(indicating). He invented it. But he also began the work,**
 24 **early work, on unidirectional airflow and protecting**
 25 **patients. And subsequent studies over the last several**

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1 **decades have shown it to be very important in protecting the**
 2 **patient.**

3 MR. FARRAR: Your Honor, can I pull over the board
 4 and draw on it?

5 THE COURT: Well, sure. Go ahead.

6 MR. FARRAR: We'll do it at the lunch break.

7 THE COURT: It's finding a location that doesn't
 8 block everybody's view that's a challenge.

9 MR. FARRAR: We'll do it at break and we'll figure
 10 it out. It will be easier.

11 BY MR. FARRAR:

12 Q. You talked about force field -- sort of a force field.

13 I think that's also known as a sterile field. Is that
 14 right?

15 A. **Yes, sir.**

16 Q. That's kind of the professional term for it?

17 A. **Yes, sir.**

18 Q. All right. Tell me where the sterile field, if you can
 19 draw on this -- I'll clear out what you've got -- tell me
 20 where the sterile field is.

21 A. **Okay. So this is the operating room table (indicating).**

22 **That's ground zero. That's where the patient is. And I**
 23 **like to say it's all about the patient, nothing else.**

24 **Everything we do is about the patient. So we want to**
 25 **protect the patient. That's ground zero, the sterile field.**

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1 **Anything below this is not sterile, is not ultra-clean.**
 2 **And often you'll have tables that are used in the**
 3 **operating room, and those are in the sterile field as well.**
 4 **This table is out of the sterile field, but you can think of**
 5 **that gray zone as the sterile field. If this table were in**
 6 **here, there would be a surgery tech standing next to it, and**
 7 **it would be covered with sterile drapes that they go to**
 8 **school to learn how to do. That's the biggest part of their**
 9 **training, is learning how to steriley drape tables and**
 10 **sterilely drape patients. They spend a lot of time going**
 11 **over that. They're very good at it. Very proud of the**
 12 **surgery techs I work with. They do a fantastic job**
 13 **protecting our patients.**

14 Q. I put up another slide that shows the red below the
 15 operating room table. Would you consider that area sterile
 16 or is it not sterile?

17 A. **I think that's a pretty good pictorial of what's not**
 18 **sterile. Basically, the reason why surgeons have their**
 19 **hands up you see in TV -- they don't necessarily have them**
 20 **up like this, but --**

21 Q. That's for the shows, right?

22 A. **Yeah. But he can be down here about waist level.**
 23 **Anything between waist or table level is not sterile. It's**
 24 **where it's a danger zone.**

25 Q. Are surgeons careful not to have anything that's below

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1 **Q.** The nurse anesthetist took a break, is that unusual in
 2 your practice?
 3 **A.** That's very common. That's usual. In fact, it's a
 4 running joke among surgeons that we make fun of them
 5 anesthesia folks because they always have to have a lunch
 6 break, and they always have to have bathroom breaks and
 7 that's what they do. And, you know, they're working all
 8 day. At least after I get done with a case, I can go sit
 9 down in the lounge, but they actually, they got to keep
 10 getting patients back, so they rightfully deserve to have
 11 the breaks, but we make fun of them for that.

12 But that's what they do. So when they need to go
 13 to the bathroom, they get relieved. When they need to go to
 14 the lunch, they get relieved, and that's standard care
 15 across America.

16 **Q.** Is there anything unusual about it?

17 **A.** There's nothing unusual about it.

18 **Q.** There was questions regarding a rep from the
 19 manufacturer of the prosthesis in the room?

20 **A.** Correct.

21 **Q.** Do you typically have reps in the room when you're doing
 22 hip replacement surgery?

23 **A.** For joint replacements every case.

24 **Q.** Why?

25 **A.** The representative knows all the vital points about the

1 everything is sterile, and no human is going in and out.
 2 But right now the best we have is what you just described,
 3 and we have to work with that. And so that's why we create
 4 an OR to diminish the effects of that. And just because
 5 it's like that, it's not a license to make it worse.

6 **Q.** When you say you create an OR to combat the effects,
 7 what are you talking about?

8 **A.** Going back to Sir John Charnley, who was united over his
 9 work on this, creating unidirectional airflow that protects
 10 the patient via this force field of getting the particles,
 11 the skin cells that are floating, the dust that is floating
 12 getting away from the patient and out to the return vents.
 13 And that's one of the reasons, that's the main reason we
 14 have that because we have to have human activity in the
 15 operating room. I have to be able to move my arms to do a
 16 surgery. I have to have a scrub nurse who can go from table
 17 to handing me an instrument. I have to have a circulator
 18 who can go get things that are necessary. It's --
 19 the anesthesiologists have to take breaks. Those are all
 20 the things that are standard of care, but it's not a license
 21 to make things worse.

22 **Q.** You were asked a question about whether the patient's
 23 skin is a major source of bacteria. And you wanted to give
 24 an explanation, and you didn't get a chance to, but you do
 25 now, so I want to let you explain what you wanted to say

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1 prosthesis, so when you're putting this in, they know where
 2 the boxes are that contain the components that are a few
 3 millimeters different. They can answer questions about
 4 factory specifications that may or may not be right on the
 5 -- might not be available to the surgeon right there other
 6 than through the representative. They make sure that the
 7 prosthesis is the correct box is being chosen to open for
 8 the surgery.

9 They, in my practice, they will come into my
 10 clinic, and they will look at the x-rays of the patients I'm
 11 about to operate. They'll make measurements and go over the
 12 case, and we'll come up with a plan for the next day.

13 They're actually a really vital part of the joint
 14 replacement care, and so that is typical for them to be in
 15 the room.

16 **Q.** Would you consider it part of the standard of care?

17 **A.** It is definitely part of the standard of care.

18 **Q.** So the number of folks in Mr. Gareis's surgery, is that
 19 consistent with the number of people that are in and out of
 20 the surgeries that you do?

21 **A.** That is, yes, that's typical. And we're not at a point
 22 in medicine where we're sitting, going to have, you know,
 23 maybe one day, you know, maybe we'll be this space ship
 24 society where we're going to have surgeons sitting in
 25 control rooms with joy sticks. We're going to have robots,

1 about that to the jury, please.

2 **A.** So the skin is a major source of bacteria. And as far
 3 as it being a significant source, it's a significant source
 4 from the standpoint that there's not just the skin cells on
 5 your skin. We deal with the skin cells on your skin with
 6 the prep. It's the skin cells like I talked about in this
 7 room. It's the skin cells in the air, it's the skin cells
 8 on the floor. Those are in addition to the skin cells that
 9 are on your skin. It's what makes it significant is we have
 10 to figure out how to control the skin cells that are not
 11 controllable. And those are the -- and the best we can do
 12 to make them controllable is through unidirectional air. We
 13 control the skin cells on the skin through our prep and we
 14 try our best to control the skin cells through this
 15 unidirectional air through this force field which takes
 16 those cells, those particulates, that dust and pushes it out
 17 through the return vents and protects the patient, and so
 18 that's what I meant. Those skin cells carry bacteria. A
 19 significant percentage of them carry bacteria.

20 **Q.** The prosthesis, can you hold that up? How does a
 21 bacteria get from wherever it is on a skin cell onto that
 22 prosthesis during a surgery?

23 **A.** If you didn't have that force field protection from the
 24 unidirectional air, the skin cells can actually come up from
 25 the floor in the air and do that (witness indicates.)

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1 **Q.** Is that called airborne contamination?
 2 **A.** That's airborne contamination, and that is through
 3 decades of research, that is the source of intraoperative
 4 infections.
 5 **Q.** Can bacteria, do they have -- this is maybe a silly
 6 question, but do they have legs? Can they walk or jump?
 7 **A.** They have to have a vector, and the vector is something
 8 that carries it to them. And it's the air, it's the air
 9 carrying it to them. So you have to have a way to control
 10 the air, to control those skin cells from getting on to the
 11 prosthesis and that's what we do. We control it through the
 12 unidirectional air.
 13 **Q.** So if you're putting in a prosthesis like that into
 14 someone like Mr. Gareis, is it possible for bacteria that's
 15 on his skin while you're putting it in to jump on to the
 16 prosthesis?
 17 **A.** Jump on it by itself?
 18 **Q.** Right.
 19 **A.** No, it's not. It needs something to bring it there.
 20 And what's interesting is when you prep a patient's skin,
 21 the Darouiche study from 2010 the New England Journal of
 22 Medicine, a significant study, it showed that when you prep
 23 a patient's skin with the best we have, which right now is
 24 in my opinion ChloraPrep, which I use, that showed a
 25 decrease infection rate at the skin level. It didn't show a

1 BY MR. FARRAR:
 2 **Q.** I want to, it's sort of a thick book, but I'm going to
 3 turn your attention if you would on the bottom to page 115.
 4 **A.** I think I found it this time.
 5 MS. PRUITT: Which number is that?
 6 MR. FARRAR: It's question 2 on page 115.
 7 MS. PRUITT: Where is the page?
 8 THE WITNESS: Oh, I see it.
 9 BY MR. FARRAR:
 10 **Q.** Do you see where I'm looking, do you see question 2?
 11 **A.** I do.
 12 **Q.** All right. What's question 2 say?
 13 **A.** "Do numbers of bacteria in the operating room
 14 environment correlate directly with the probability of SSI?
 15 Surgical site infection.
 16 **Q.** And can you read what the consensus --
 17 REPORTER: I'm sorry.
 18 **A.** SSI means surgery site infection.
 19 **Q.** And if you would read what the consensus is?
 20 **A.** "We recognize that airborne particulate bacteria are a
 21 major source of contamination in the OR environment and that
 22 bacteria shed by personnel are the predominant source of
 23 these particles. The focus of our" -- do you want me to
 24 keep going?
 25 **Q.** No, I really want to ask you about the justification and

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1 decrease infection rate at the deep joint. So it shows that
 2 it's the air infecting the deep joint. It's not the skin
 3 because if it had been the skin, that study would have shown
 4 an increased infection rate of deep joints, and it didn't.
 5 **Q.** So airborne contamination is what infects people for
 6 deep joint infections?
 7 **A.** Airborne contamination dating back decades, decades of
 8 research.
 9 MR. FARRAR: Your Honor, may I approach?
 10 THE COURT: You may.
 11 BY MR. FARRAR:
 12 **Q.** The international consensus we talked about yesterday
 13 from both I asked you some questions and Ms. Pruitt asked
 14 you some questions about it, and this is the group of four
 15 hundred or so that get together every couple of years and
 16 discuss the best practices to prevent deep joint infections,
 17 correct?
 18 **A.** Yes, sir.
 19 **Q.** And I think I asked you this, but you find it
 20 authoritative and relied on it for opinions in this case,
 21 right?
 22 **A.** I did.
 23 MR. FARRAR: I'm going to ask questions on this,
 24 do you have any objection?
 25 MS. PRUITT: No. It's not that I don't want to.

1 it says, "air is a potential source of contamination in the
 2 OR," and this is the part that I wanted to focus on.
 3 **A.** Okay.
 4 **Q.** "Studies have demonstrated that the number of airborne
 5 bacteria around the wound is correlated to the incident of
 6 periprosthetic joint infection." Can you tell the ladies
 7 and gentlemen of the jury what that means?
 8 **A.** So it's the airborne bacteria that is correlated with
 9 the infection in the joint. It's airborne bacteria that is
 10 affecting the deep joint. It's not the skin. It's not the
 11 skin on the patient's skin. It's the airborne bacteria that
 12 are floating on skin or particles or dust that are then
 13 making their way into the wound and infecting that joint.
 14 **Q.** I want to shift gears. You were asked some questions
 15 about Mr. Gareis having a prior total hip replacement on his
 16 other hip, and he had two other in his revision surgeries.
 17 And the questions were something about him using the Bair
 18 Hugger and not getting the infections in those, and I want
 19 to ask you is that significant to you as an orthopedic
 20 surgeon that he used the Bair Hugger in other instances and
 21 did not get an infection?
 22 **A.** It is. To answer your question, that's not significant
 23 to me.
 24 **Q.** Why not?
 25 **A.** Because like I said, the operating room is not a robotic

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1	Q. Well, actually, that raises a good point I would like	1	exchange genetic material among themselves. So compared to
2	to clarify for the Ladies and Gentlemen of the Jury. You	2	an organism such as the coagulase positive or
3	were here when Dr. Presnal's deposition was played,	3	Staphylococcus aureus that I showed you, that would tend to
4	correct?	4	grow much faster. It has enzymes in it that allow it to
5	A. Yes.	5	burrow through tissue much more rapidly. So you are going
6	Q. And do you recall him talking about the fact that	6	to have more clinical signs and symptoms with a Staph
7	looking at the stain of the bug he couldn't tell where it	7	aureus infection than you would have with a Staphylococcus
8	came from?	8	epidermidis infection.
9	A. Correct.	9	Q. Okay. I would like to direct your attention to
10	Q. Okay. What did that mean to you?	10	Plaintiffs' Trial Exhibit 1607, slide 35, which we would
11	A. Well, if you look at this plate or if you looked at a	11	offer for demonstrative purposes.
12	stain, what's called a Gram stain that stains these bugs so	12	And you've mentioned biofilm. Can you describe
13	you can see them under a microscope, it doesn't tell you	13	this visual for the Ladies and Gentlemen of the Jury in
14	anything about where they came from. Unless I told you	14	connection with the creation of biofilm and how it can
15	where I cultured them from, you would have no idea where	15	smolder for a long time before exhibiting itself?
16	they were even at.	16	A. Sure. So on this slide, if you thought of that gray
17	Q. But that's a different issue than when you were finding	17	almost like table as an implant, the organism in 1 is
18	out when you were inoculated with the bug, correct?	18	landing on it; and when they land on it, they attach
19	A. Correct.	19	themselves and then they produce what's called an
20	Q. And that's the investigation that you did?	20	exopolysaccharide or biofilm or, as Dr. Stonnington said,
21	A. Correct.	21	slime that covers themselves and, as he mentioned, that
22	Q. Okay. If we could direct your attention to	22	coverage or biofilm or slime helps to protect them. It's a
23	Plaintiffs's demonstrative Exhibit 1607, slide 30, which we	23	defense mechanism for the organism. The organism is saying
24	would offer for demonstrative purposes.	24	I want to live here, I want to grow and proliferate here,
25	What are we looking at here, Dr. Jarvis?	25	which we as humans don't want it to do, but it wants to do,
	598		600
1	A. So this is just showing you that once you have this	1	so it has developed mechanisms to help it do that.
2	Staphylococcus, you could do a Gram stain and see that it's	2	One of the ways is to put this shield or
3	a Gram-positive, so it will be a purple-looking bug under a	3	fortress, as Dr. Stonnington talked about, through this
4	microscope. Then you do this very simple test in the test	4	slime or biofilm that then prevents the blood and our
5	tube called a coagulase test. And if it's coagulase	5	immune system cells from getting to it or the antibiotics
6	positive, that means it's Staphylococcus aureus. If it's	6	in our blood getting to it or you need very high levels of
7	coagulase negative, and we have heard coagulase negative	7	antibiotic to try to drive it in. As you can see, they
8	Staphylococci, it puts it into that category. And of all	8	gradually produce in no. 2 a little bit of slime and then
9	of the coagulase negative Staphylococci, Staphylococcus	9	in no. 3 it's even more; and within that slime, they are
10	epidermidis is the most common one.	10	exchanging genetic, basically talking to one another. It's
11	Q. Okay. And we've heard a lot of testimony about the	11	a community. They're talking to one another. They're
12	fact that it's a common bug on your skin; is that right?	12	growing. If they feel like they're growing too fast, they
13	A. Correct.	13	can send a signal to one another and say let's slow down
14	Q. Is it a common bug deep down in your hip where an	14	here.
15	implant is?	15	So they gradually grow to larger numbers, and
16	A. No. That would be sterile.	16	then at some point they break through the slime and can get
17	Q. Okay. And so by what mechanism could a Staph epi bug	17	into the other tissue or get into the bloodstream.
18	end up on an implant?	18	Q. Okay. I would like to switch gears now, Dr. Jarvis,
19	A. The primary mechanism would be airborne.	19	and talk to you about the methodology that you employed in
20	Q. And there was also some testimony about the fact that	20	arriving at the conclusions and your opinions that we're
21	this is a slow-growing bug. Do you agree with that	21	going to be talking about. Okay?
22	assessment?	22	A. Okay.
23	A. Well, everything is relative, but if it's in a biofilm,	23	Q. Did you review a number of journal articles and medical
24	one of the advantages that the organism has when it's in a	24	studies?
25	biofilm is they can down regulate their growth, they can	25	A. Everything I could find.

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1	Q. Okay. How arduous was that undertaking?	1	Q. Okay. And what's the date of this?
2	A. Well, it took a lot of time because I tried to review	2	A. January 2017.
3	as much of the literature as I could find, both in terms of	3	Q. Okay. Do you consider the Infection Control and
4	normothermia, risk factors for prosthetic joint infection,	4	Hospital Epidemiology journal to be authoritative?
5	the impact of particles, correlation between particles and	5	A. Yes.
6	bugs or colony-forming units, virtually everything I could	6	Q. And is it something that folks like yourself would rely
7	try to find on the subject.	7	upon in connection with their work?
8	Q. Okay. And did you also review a number of expert	8	A. Yes. This is the one I mentioned that I was the editor
9	reports both by the plaintiffs as well as the defense	9	of.
10	experts?	10	Q. Okay. And did you rely on this article in forming your
11	A. Correct. Yes.	11	opinions in this case?
12	Q. Okay. And did you review deposition testimony and	12	A. Yes.
13	documents that were exchanged between the parties in the	13	MS. CONLIN: Okay. We would offer Plaintiffs'
14	case?	14	Exhibit 530 under 803(18).
15	A. Yes.	15	THE COURT: You may proceed.
16	Q. Okay. So describe the methodology that you did in	16	MS. CONLIN: Thank you, Your Honor.
17	arriving at your conclusions here.	17	BY MS. CONLIN:
18	A. Well, first was reading Mr. Gareis's medical records,	18	Q. If you could just describe what they were attempting to
19	and then was looking at all of the peer-reviewed published	19	do in this study, Dr. Jarvis?
20	literature that I could find that addressed the subject in	20	A. Well, this is the study that I mentioned to you by
21	evaluating those papers, and then looking at expert reports	21	Darouiche from the VA in Houston where he randomized
22	and depositions to see do they substantiate, conflict with	22	patients to two different arms. One was -- I mentioned
23	what's in the literature, and then reaching an opinion	23	vacuum cleaner. I probably carried that analogy a little
24	balancing all of that.	24	bit too far. It looks like the end of a vacuum cleaner,
25	Q. Okay. Now, you mentioned before that you had seen --	25	kind of like that (indicating), but it's actually not
	602		604
1	or have you seen scientific literature relating to whether	1	sucking. It's blowing HEPA-filtered air. So HEPA
2	airborne contamination can cause prosthetic joint	2	filtration, which is what operating rooms have as usually
3	infections like the one that Mr. Gareis suffered from?	3	one of the last filters before it comes into the operating
4	A. Yes.	4	room, they filter out 99.97, so almost 100 percent of
5	Q. Okay. Is that something that is well recognized?	5	particles that are 0.3 microns or bigger.
6	A. Absolutely.	6	Now, to give you a sense of 0.3 microns, if I
7	Q. Okay. I would like to direct your attention,	7	took a hair off of any one of you and just held it up, it's
8	Dr. Jarvis, to Plaintiffs' Exhibit 795. And that was the	8	less than 40 microns. And we're talking about .3 microns.
9	reference we talked about before, correct, Doctor?	9	So it gets very small particles and anything bigger than
10	A. Correct.	10	that and stops it from getting into the room.
11	Q. And I think you read the last sentence about that the	11	In this study they used a device that they put
12	results obtained through that study by far found that the	12	right next to the incision that looks a little bit like the
13	greater part of bacterial wound contamination in operations	13	end of a vacuum cleaner, and it blew this HEPA-filtered air
14	for joint replacement is derived from air; is that correct?	14	over the incision. So it's similar to the air coming down,
15	A. Correct.	15	the laminar flow or unidirectional airflow, where the air
16	Q. And did that weigh on your opinion?	16	is coming down, having basically a protective shield to
17	A. Yes.	17	blow particles away from the operative field. This is
18	Q. Okay. I would like to direct your attention as well to	18	blowing it across the incision during the time they're
19	Plaintiffs' Exhibit 530. And what's the title of	19	doing the surgery.
20	Plaintiffs' Exhibit 530?	20	So the question these authors were asking was, if
21	A. Association of Airborne Microorganisms in the Operating	21	we make the area right around the incision really, really,
22	Room With Implant Infections: A Randomized Controlled	22	really super clean, what impact is it?
23	Trial.	23	Q. Okay. And if I can stop you there, if you can look at
24	Q. And where was this published?	24	the first page of this Darouiche study, Dr. Jarvis, on the
25	A. In Infection Control and Hospital Epidemiology.	25	left-hand side, the very last sentence starting with

<p style="text-align: right;">625</p> <p>1 room table and what does it do to those, and it gives us a 2 visual of what it's doing to those. 3 Q. Okay. Did you also review the report or the McGovern 4 study? 5 A. Yes. 6 Q. Okay. And we're going to talk about that a little bit. 7 You understand that Dr. Samet is coming next week on that, 8 but I just want you to briefly touch upon why you thought 9 that study was important to the opinions that you're 10 reaching here. 11 So if I could direct your attention to 12 Plaintiffs' Trial Exhibit 93. 13 MR. COREY GORDON: Your Honor, we want to note 14 our objections under 402 and 403 and MIL 1. 15 THE COURT: You may proceed. 16 MS. CONLIN: Thank you. 17 BY MS. CONLIN: 18 Q. Do you have it, Doctor. 19 A. Yes, ma'am. 20 Q. This is known as the McGovern study; is that right? 21 A. Correct. 22 Q. And it was published in the Journal of Bone and Joint 23 Surgery, correct? 24 A. Yes. 25 Q. Okay. And it was authored by Dr. McGovern from the UK,</p>	<p style="text-align: right;">627</p> <p>1 versus some other way of warming? 2 A. Yes. 3 Q. Okay. And what did those authors find? 4 A. That the risk of an infection was increased by a factor 5 of 3.8 over the other warming system. Odds ratio was 3.8. 6 Q. What is -- Dr. Samet is going to talk about this next 7 week, but the way I think about it from a lay person 8 standpoint, does that mean you have a 380 -- 9 THE COURT: Use the microphone. 10 MS. CONLIN: Sorry, Your Honor. Sorry. 11 BY MS. CONLIN: 12 Q. -- 380 increase or times increased risk, or how would 13 you describe an odds risk ratio of 3.8 to those of us who 14 are not epidemiologists? 15 A. You have a 380 times greater risk of having an 16 infection. 17 Q. And if I could direct your attention to page 7 of 18 Plaintiffs' Exhibit 93. 19 A. Okay. 20 Q. And I would like you to look at the first full 21 paragraph there after they talk about this 3.8 increased 22 risk, and it says, "This study does not establish a causal 23 basis for this association." 24 What does that mean? 25 A. Well, I think they realize that, you know, it's not a</p>
<p style="text-align: right;">626</p> <p>1 correct? 2 A. Correct. 3 Q. And then there were also some individuals from 4 Minnesota, including Mr. Albrecht and Dr. Belani and 5 Dr. Nachtsheim, correct? 6 A. Correct. 7 Q. Okay. And was this a study that was comparing 8 surgical -- I'm sorry -- deep joint infections or PJJIs or 9 DJIs, you consider those interchangeable, right? 10 A. Correct. 11 Q. Comparing the infection rate when a Bair Hugger was 12 used versus a different warming modality; is that right? 13 A. That was one part of the study, yes. 14 Q. Okay. And I would like to direct your attention to the 15 discussion which is on page 5. 16 A. Okay. 17 Q. And if you could just read the first sentence and what 18 impact, if any, that sentence had to you in connection with 19 your conclusions in this case? 20 A. "Forced air warming was found to have a significant and 21 disruptive impact on the clean airflow patterns over the 22 surgical site compared to conductive fabric warming which 23 had no detectable effect." 24 Q. Okay. And did the McGovern authors also look at 25 whether you got more infections if you used the Bair Hugger</p>	<p style="text-align: right;">628</p> <p>1 huge number of patients, and it's very difficult in most 2 studies to show a causal relationship. 3 Q. Okay. Is that language that you see often? 4 A. Very often, yes. 5 Q. Okay. And what does it mean that there is an 6 association versus causal basis? 7 A. Well, association means that they've obviously found a 8 statistical association and that what they can't say is it 9 is the only cause. 10 Q. Okay. And so is it -- and was this a randomized 11 control trial? 12 A. No. 13 Q. It was an observational study? 14 A. Correct. 15 Q. And what import does that difference have to someone 16 such as yourself? 17 A. Well, theoretically randomized control trial, as we 18 mentioned, that controls for confounding variables is, can 19 be the best type of study. That's not to say that some 20 randomized control trials aren't faulty as well, but 21 observational studies tend to be, tend to suffer more from 22 the, that confounding variables issue and that unless you 23 collect an enormous amount of data so you can kind of -- 24 and have a large number of patients so you can analyze all 25 those little tiny cells, you can't necessarily control for</p>

	629		631
1	all those different confounding variables.	1	the Bair Hugger increases particles over the surgical
2	So they're not as powerful a study, but they, to	2	field. We know that increased particles causes increased
3	me before/after studies, as well as case control and cohort	3	bacteria. Stocks just showed the combination, correlation
4	studies that are less powerful than a randomized control	4	between the two, and that increased bacteria causes
5	trial, but most of the time in epidemiology what you find	5	increased risk for a prosthetic joint infection.
6	is, if you find it in a well designed observational case	6	So we have a variety of studies that answer each
7	control or cohort study and you subsequently do a huge	7	one of these questions, and when you put them all together,
8	randomized control study, you find the same thing.	8	you get a picture similar to what Dr. Elghobashi has shown
9	Q. So we have kind of put together a bunch of pieces of	9	with his CFD model that illustrates why the Bair Hugger
10	the puzzle, and I would kind of like to summarize it before	10	will increase the risk of prosthetic joint infections.
11	we get to Mr. Gareis.	11	Q. Okay. Now, you were here during opening, and you heard
12	Have you had a demonstrative prepared that would	12	Mr. Blackwell say that the Bair Hugger was safe because of
13	aid the Ladies and Gentlemen of the Jury in understanding	13	studies, correct?
14	how you put these pieces together?	14	A. Correct.
15	A. Yes.	15	Q. I think he said the most studied forced air warming
16	MS. CONLIN: Your Honor, we would offer for	16	device in the history of the planet. Do you recall that?
17	demonstrative purposes 1607, slide 16.	17	A. Yes.
18	THE COURT: Has it been amended since yesterday?	18	Q. Okay. Have you looked at the studies that 3M has
19	MS. CONLIN: It has, Your Honor.	19	relied upon for its position that the Bair Hugger is safe?
20	THE COURT: Okay.	20	A. Yes.
21	MR. COREY GORDON: 13?	21	Q. Okay. I would like to direct your attention to
22	MS. CONLIN: 16.	22	Plaintiffs' Trial Exhibit 1, the Zink study.
23	MR. COREY GORDON: I apologize. No objection,	23	A. Yes.
24	Your Honor.	24	Q. And is that one of the studies that 3M has relied upon?
25		25	A. Yes.
	630		632
1	BY MS. CONLIN:	1	Q. Can you describe for the Ladies and Gentlemen of the
2	Q. So explain, we have kind of gone through all these	2	Jury what this study was about?
3	different pieces. Explain sort of how these all wrap up in	3	A. This study involved eight healthy volunteers.
4	connection with your opinion that the use of a Bair Hugger	4	Q. Let me stop you right there. There was only eight
5	increases the likelihood that you're going to get a PJI?	5	volunteers in the Zink study?
6	A. I think what we find in clinical medicine is, advances	6	A. Yes, eight volunteers, 20 to 25 years of age. Not
7	are made kind of a step at a time, and we know the first	7	exactly our age, Mr. Gareis, and they then took them into
8	one. Bacteria cause infection. Micro organism cause	8	an operating room and had them lay on a table. And then
9	infection. If you don't have the micro organism, you're	9	they used a lower body warming device.
10	not going to get an infection, period.	10	So Mr. Gareis's was an upper body. They're using
11	We also know now from a variety of both human	11	a lower body. They placed a sterile drape, and then they
12	studies and animal studies that a smaller inoculum of	12	did testing during two hours when it was off and two hours
13	bacteria will cause an implant infection or a prosthetic	13	when it was on using culture plates that they set on their
14	joint infection or a PJI, compared to trying to	14	abdomen.
15	experimentally cause an infection with bugs without an	15	Q. And what was the date of the study?
16	implant takes thousands, if not tens or hundreds of	16	A. The date of the --
17	thousands, more organisms.	17	Q. Or the date of the publication?
18	We know, Darouiche study shows it eloquently,	18	A. This is from 1993.
19	that airborne contamination can cause a PJI. We know the	19	Q. Okay.
20	environment of use of any device is very important. If I	20	THE COURT: That was leading.
21	have a device that produces 50 percent infection rates, but	21	MS. CONLIN: It was, Your Honor. I apologize.
22	this is the operating room, and I have it outside the	22	BY MS. CONLIN:
23	operating room, who cares?	23	Q. Do you know what the date of the study was, Dr. Jarvis?
24	If I bring it into the operating room, you're	24	A. Yeah. I'm trying to see if there was a month, but it's
25	going to care. We know multiple studies have shown that	25	1993.

11 BEFORE THE HONORABLE JOAN N. ERICKSEN
12 UNITED STATES DISTRICT COURT JUDGE

(JURY TRIAL - VOLUME IV)

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P R O C E E D I N G S

(9:04 a.m.)

THE COURT: Dr. Jarvis, come on up.

Good morning, everybody. Please be seated.

You're still under oath from yesterday. You can go ahead and take the seat.

And, Ms. Conlin, whenever you're ready.

MS. CONLIN: Yes, thank you, Your Honor.

DIRECT EXAMINATION

BY MS. CONLIN:

Q. Good morning, Dr. Jarvis.

A. Good morning.

Q. I want to just finish up on a couple points that we're dealing with yesterday. I'd like to talk to you a little bit more about the studies that have been cited in this case.

I'd like to add a column for orthopedic procedures, and so could I direct your attention to the Zin article first. Do you know how many of those were orthopedic procedures?

A. Zero.

Q. And how about in the Huang study?

A. Zero.

Q. How about Moretti?

A. 20.

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1 Q. And how about Hall?

2 A. Zero.

3 Q. And in the interest of completeness, I'd like to add one

4 other study, the Oguz study, if you could look in your book,

5 sir, at Trial Exhibit 635. And is this article entitled,

6 "Airborne Bacterial Contamination during orthopedic surgery

7 a randomized control trial?

8 A. Correct.

9 Q. What did they find in that trial with respect to whether

10 there was an increase in bacteria at the surgical site when

11 the Bair Hugger was used?

12 A. Well, they did agar plates around the operating room,

13 and the one that was closest to the patient, wasn't really

14 real close, but the closest is table or plate 4 in the study

15 and that had an increase that almost reached statistical

16 significance.

17 Q. And how many patients were in the Oguz study?

18 A. There were a total of 80 patients that were randomized

19 to the forced air warming Bair Hugger versus an electric

20 blanket, and then they were divided into laminar flow and

21 non-laminar flow, but the bottom line is of these were all

22 minor orthopedic procedures so not implant procedures and

23 there was only one total knee.

24 Q. How many patients total?

25 A. In the forced air warming, 40.

<p style="text-align: right;">762</p> <p>1 Q. Right. But in terms of the number of particles in each 2 of those categories, it plummets logarithmically when you go 3 from 0.3 to 0.5 to 5, right?</p> <p>4 A. Well, it does decrease. But if that 2.8 lands on your 5 prosthetic joint, that's important. It doesn't take 10 of 6 the 4.</p> <p>7 Q. So is it your testimony that you're taking these studies 8 that didn't find any -- didn't look or at least didn't 9 report an increase in 10 micron particles as a result of the 10 Bair Hugger and you're just saying, well, that's okay, they 11 must have -- that must mean that 10 micron size particles 12 increase too; and, hey, there are these studies that say if 13 you have 10 micron particles or greater, there is a positive 14 correlation with bacteria; well, therefore, the Bair Hugger 15 increases bacteria?</p> <p>16 A. Well, there was a lot of questions in that one. You 17 want to reword that?</p> <p>18 Q. You don't have a single study that demonstrates by any 19 methodology that the Bair Hugger increases particles over 20 the surgical site -- particles over the surgical site of 21 greater than 10 microns, right?</p> <p>22 A. Greater than 10 microns --</p> <p>23 Q. Equal to or greater than.</p> <p>24 A. Well, the Stocks study looks at greater or equal to 10 25 microns.</p>	<p style="text-align: right;">764</p> <p>1 bacteria correlations and only concluded from their data 2 that 10 microns or greater correlated, you've concluded that 3 no, actually, there is a correlation with 5 micron and up?</p> <p>4 A. Well, are you telling me that in Table 2 where it says 5 the variable is 5 to 9.99 and the P value is 0.015 that I 6 should ignore that, that it's irrelevant, that they report 7 it and we don't want to look at some of the data?</p> <p>8 Q. You know, this whole thing about particle and bacteria 9 might be kind of confusing. Why would anybody in an 10 operating room care about counting particles and seeing if 11 they measure up with bacteria? Do you know?</p> <p>12 A. Well, I think there are probably several reasons why 13 they would want to do that. One, which many of these 14 authors have pointed out in their introductions and the 15 discussion, is it would be very valuable during an 16 orthopedic implant procedure to be able to do a test during 17 the procedure that could be predictive of increased risks of 18 infection --</p> <p>19 Q. A real-time measurement?</p> <p>20 A. -- or trying to prevent that from happening.</p> <p>21 Q. That's because with the technology that's readily 22 available to hospitals, not expensive military equipment, 23 there is nothing that you can take into an operating room 24 and push a button and look at a read-out and say we've got X 25 number of bacteria, right?</p>
<p style="text-align: right;">763</p> <p>1 Q. That's right. You keep wanting to tell us that the 2 Stocks study is about the Bair Hugger. It's not, right?</p> <p>3 MS. CONLIN: I would object as argumentative, Your 4 Honor.</p> <p>5 MR. COREY GORDON: I withdraw.</p> <p>6 THE COURT: Can you rephrase.</p> <p>7 MR. COREY GORDON: Yes. Apologize, Your Honor.</p> <p>8 BY MR. COREY GORDON:</p> <p>9 Q. The Stocks study does not have anything to do with the 10 Bair Hugger, doesn't it, Dr. Jarvis?</p> <p>11 A. Correct.</p> <p>12 Q. Is there any study -- there is no study that shows that 13 the Bair Hugger increases particles of 10 microns or greater 14 over the surgical site, right?</p> <p>15 A. Well, there's none that look specifically at that issue.</p> <p>16 We have different pieces of the puzzle that are looked at in 17 various studies.</p> <p>18 Q. Okay. And so you take those studies that show maybe 19 small particles -- you say, well, that's a piece of the 20 puzzle, must be moving bigger particles, too? That's one of 21 your leaps, right?</p> <p>22 A. Well, and that's where Dr. Elghobashi in his model can 23 help fill in that gap, where studies haven't been done.</p> <p>24 Q. Okay. And then you take like the Stocks study, and even 25 though the authors were specifically looking for particle</p>	<p style="text-align: right;">765</p> <p>1 A. Right. Turn that machine off or let's not do surgery 2 today, yeah.</p> <p>3 Q. But they're hand-held units, you go in and push a button 4 and it tells you the number of particles, right?</p> <p>5 A. Correct.</p> <p>6 Q. Doesn't tell you anything about whether the particles 7 you're counting are completely inert, maybe a little 8 bacteria or a lot of bacteria? Tells nothing about 9 bacteria, right?</p> <p>10 A. Well, that's not true. Stocks right here does.</p> <p>11 Q. But that's why Stocks and all these other researchers 12 have been trying to correlate that, because if they could 13 correlate, then OR personnel could be confident that if they 14 take a particle measurement and whatever they decide is 15 relevant, things are okay or say we better stop and see 16 what's going on?</p> <p>17 A. Absolutely, why we shouldn't ignore it.</p> <p>18 Q. But at least three researchers in papers that you read 19 published in peer-reviewed journals concluded that you just 20 can't correlate particles?</p> <p>21 A. And, as I said, those three papers if you look carefully 22 at them use different methodologies, and they don't do six 23 or seven or eight or ten particle sizes. They do one or two 24 or at most three. And, as a result, they are loading all 25 the small particles in with the bigger particles and,</p>

<p>778</p> <p>1 with the Bair Hugger turned on?</p> <p>2 A. It's interesting all three of these studies basically put</p> <p>3 the agar plates in the same place. Except the one that was</p> <p>4 on the abdomen, they were around the outside of the room and</p> <p>5 then one somewhat proximate to the patient but not really</p> <p>6 near the surgical site.</p> <p>7 Q. Well, Doctor, wouldn't you agree that when you are doing</p> <p>8 surgery, you probably don't want to have agar plates right</p> <p>9 in the way?</p> <p>10 A. Well, I don't know. Darush put the particle counter</p> <p>11 right next to the surgical incision in HEPA filtered air.</p> <p>12 Q. Let's talk about McGovern.</p> <p>13 A. And it is interesting, if you look at --</p> <p>14 Q. There's no question pending now.</p> <p>15 A. Don't want to look at the data? Okay.</p> <p>16 Q. If you turn to P93.</p> <p>17 A. 93?</p> <p>18 Q. P93. It's McGovern. You already talked a little bit</p> <p>19 about this with the bubble part of it. There was another</p> <p>20 part of it. After they did the bubble study, they took a</p> <p>21 look at infection rates before and after and made some</p> <p>22 changes at the hospital, right?</p> <p>23 A. Right.</p> <p>24 Q. Okay. This would be what's called an time -- an</p> <p>25 interrupted time series observational study?</p>	<p>780</p> <p>1 In addition, we were unable to consider all</p> <p>2 factors that have been associated with SSI, as the details</p> <p>3 of blood transfusion, obesity, incontinence, and fitness for</p> <p>4 surgery which have been identified elsewhere as important</p> <p>5 predictors for deep infection were not sufficiently detailed</p> <p>6 in the medical record. Did I read that correctly?</p> <p>7 A. Correct.</p> <p>8 Q. So that's really saying two things. They were changing</p> <p>9 other infection control practices during this time period,</p> <p>10 right?</p> <p>11 A. Well, they said there were none after February 2010, so</p> <p>12 not during the whole time period, no.</p> <p>13 Q. Okay. And if you want to take the time, we can go</p> <p>14 through it, but the Bair Hugger, the time period of the Bair</p> <p>15 Hugger that they were looking at went from July 2008 to</p> <p>16 March of 2010, so there were lots of changes going on before</p> <p>17 the Bair Hugger -- during the Bair Hugger period?</p> <p>18 A. Well --</p> <p>19 Q. Stopped making changes --</p> <p>20 A. -- you're characterizing it as a lot. I don't know</p> <p>21 that's the case. They haven't listed them. They just say</p> <p>22 that there were none after February 2010. They don't say we</p> <p>23 did four before 2010 or 10 or 20 or 1.</p> <p>24 Q. Dr. Jarvis, you know that they changed the</p> <p>25 thromboprophylaxis back and forth, that's an anti-blood</p>
<p>779</p> <p>1 A. Definitely an observational study, yeah.</p> <p>2 Q. And one of the big problems with interrupted time series</p> <p>3 is if you look at one period in time and another period in</p> <p>4 time and try to just isolate out one thing when there's been</p> <p>5 all sorts of changes on both sides, you can't really ascribe</p> <p>6 any correlation or causation to any change in one number,</p> <p>7 right?</p> <p>8 A. I don't think I would agree with that characterization.</p> <p>9 Obviously a confounding variable is only important if it's a</p> <p>10 confounding variable. If it has nothing to do with the</p> <p>11 price of tea in China, then obviously it doesn't matter if</p> <p>12 it changed. It has to be related to the event you are</p> <p>13 looking for and, in this case, prosthetic joint infections.</p> <p>14 Q. In this case, the authors on page 0007 said this study</p> <p>15 does not establish a causal basis for this association,</p> <p>16 right?</p> <p>17 A. Correct.</p> <p>18 Q. Let's go on, though. They say, Although the</p> <p>19 demographics were similar between the patient groups in</p> <p>20 items of risk factors for infections, the data are</p> <p>21 observational and may be confounded by other infection</p> <p>22 control measures instituted by the hospital. For example,</p> <p>23 changes were made to the antibiotic, thromboprophylaxis</p> <p>24 protocols used during the study, although no infection</p> <p>25 control changes were made after February 2010.</p>	<p>781</p> <p>1 clot, right?</p> <p>2 A. Right. And the thromboprophylaxis is given after</p> <p>3 surgery.</p> <p>4 Q. And they had some problems with it with increased return</p> <p>5 to theater that they switched right back after only seven</p> <p>6 months?</p> <p>7 A. And there have been studies showing no impact on</p> <p>8 prosthetic joint infections too.</p> <p>9 Q. And there have been studies showing that it increases</p> <p>10 deep joint infections, aren't there?</p> <p>11 A. Well, there were some randomized controlled trials</p> <p>12 showing the opposite too.</p> <p>13 Q. But you just want to talk about the ones that support</p> <p>14 the position that you are advocating here, right?</p> <p>15 A. No, I'm saying that they're both.</p> <p>16 Q. Okay.</p> <p>17 A. That the -- go ahead.</p> <p>18 Q. If you look at figure -- or Table 2, excuse me, the only</p> <p>19 comparison they did in terms of possible infection control</p> <p>20 changes, even though they mentioned some as examples, is</p> <p>21 they did a univariate analysis between the Bair Hugger and</p> <p>22 when they switched over to a different warming device,</p> <p>23 right?</p> <p>24 A. Correct.</p> <p>25 Q. They didn't do a multi varied analysis like you and your</p>

	782		784
1	colleagues did after you did the uni varied analysis in that	1	Q. And the first full paragraph on the bottom of the
2	1990 study, right?	2	right-hand column, you wrote, For most SSIs, the source of
3	A. Correct.	3	pathogens is the endogenous flora of the patient's skin,
4	Q. And there are a whole bunch of things that they didn't	4	mucous membranes, or hollow viscera. Did I read that right?
5	even look at, they couldn't look at, because they didn't	5	A. Correct.
6	have the data, and one of those was fitness for surgery,	6	Q. And you go on to say, When mucus membranes or skin is
7	right?	7	incised, the exposed tissues are at risk for contamination
8	A. How ever they evaluate that, yes.	8	with endogenous flora. Did I read that right?
9	Q. That's ASA, right? They do not -- they don't call it	9	A. Yes.
10	that in England, but ASA is a measure of fitness for	10	Q. And you mentioned it yesterday, endogenous means what we
11	surgery, right?	11	have on our bodies, in our bodies, it's our bacteria, right?
12	A. Could be, yes.	12	A. Correct.
13	Q. And after you went through all of your univariate	13	Q. It's what the patient brings to the table?
14	analyses of all those factors that you carefully examined	14	A. Correct.
15	and carefully culled out of the records and interviews and	15	Q. Okay. So in 1999, when you were working for the CDC and
16	examinations, you did the uni varied analyses of all those	16	you reviewed all the literature and did that CDC gold
17	factors, you found I think you said ten that might have been	17	standard and you were trying to give guidance to
18	contributors, then you did a uni -- a multi varied analysis	18	practitioners who were actually on the firing line, you told
19	and you found that fitness for surgery as measured by the	19	them that for most SSIs, the source of pathogens is the
20	ASA was significant difference in doctor X's client or	20	endogenous flora, what the patient brings to the table?
21	patient group than --	21	A. Right. And that goes back to what we talked about
22	A. Well, an ASA --	22	earlier, that if you look at all SSIs, remember those three
23	Q. The --	23	categories, two-thirds of SSIs are that top incisional
24	A. -- equal to or greater than three.	24	layer.
25	THE COURT REPORTER: Could you say that again?	25	Q. Yeah.
	783		785
1	THE WITNESS: An ASA equal to or greater than	1	A. So the endogenous flora is important for that, and that
2	three.	2	is why it is the most common is because the most common site
3	BY MR. COREY GORDON:	3	of infection is not deep organ space or prosthetic joint, it
4	Q. And if you turn to P860, this is the CDC guideline for	4	is superficial incisional and that's where the patient's
5	prevention of surgical site infection from 1999, right?	5	skin is important.
6	A. Correct.	6	Q. And, Doctor, this has lots of references for each of the
7	Q. And you were the coordinator who pulled this together,	7	assertions in it, doesn't it?
8	right?	8	A. Has lots of reference.
9	A. Correct.	9	Q. References, scientific research, literature, articles at
10	Q. And you are listed as the senior author, right?	10	the back, footnotes?
11	A. Correct.	11	A. Oh, absolutely, yeah.
12	Q. And this was your -- your colleagues and the CDC's	12	Q. So for the statement that you make here when mucus
13	attempt to give the best guidance to hospitals, physicians,	13	membranes where skin is incised, the exposed tissues are at
14	and others involved in medical care for reducing surgical	14	risk for contamination with endogenous flora, you list one
15	site infections, right?	15	reference, right?
16	A. Correct.	16	A. Right.
17	Q. And that includes periprosthetic deep joint infections,	17	Q. And that would be reference number 58, right?
18	right?	18	A. Right.
19	A. It's not specific to that.	19	Q. Could you go to the reference list and just read for the
20	Q. No.	20	jury the title of that reference?
21	A. It's a general guideline, but it includes that.	21	A. 58?
22	Q. But it's not just about superficial infections, is it?	22	Q. Yep.
23	A. Oh no, absolutely not.	23	A. Roots of infection, a study of using tracer particles in
24	Q. Okay. If you turn to page 0008. I'm sorry, 0007.	24	orthopedic operating room. So it's looking at all SSIs, not
25	A. Yes.	25	just prosthetic joint infections.

<p>874</p> <p>1 average, N for Navier, S for Stokes, and that doesn't give 2 you eddy sizes or anything. It's just the simplest way to 3 do it. Most industries view that for noncritical flows. 4 Q. Is there -- what are the other two ways to do it? 5 A. So that would be the cheapest most crude way of doing 6 it. The highest end will be a direct American simulation. 7 That's like the gold standard. It has no approximation. It 8 gives you details in space and time of every eddy, 9 everything you want to know. And that's my part, my 10 research is for past 35 years in that. That's very 11 expensive and cannot do high RANS number flow because we do 12 not have bigger super computer here or in China. China has 13 the biggest but still cannot do that. So you cannot use DNS 14 for a flow of an airplane or a car. So it becomes just like 15 a microscope, it gives you details that you can use the 16 results of DNS to help RANS. And in the middle between 17 them, something called large-eddy simulation, and that's 18 what we did for this project. It is the only way to do the 19 turbulent flow in an operating room accurately and available 20 super computer can do it and that does not resolve the very 21 tiny scales because they cost so much money. Large eddies, 22 LES, large-eddy simulation, it can resolve the big eddies 23 but not the tiniest one because of the cost. 24 Q. So you first told the jury about RANS, right? 25 A. Yes, RANS. Right, yes, RANS.</p>	<p>876</p> <p>1 is in the book right in front of you. 2 A. Yes. 3 Q. And if you turn to page 12 of that document. First of 4 all, what is that document, do you know? 5 A. Page 12? 6 Q. Yes. 7 A. Yes, it's specifications. 8 Q. Do you know what this document is on the first page? 9 A. 3M Bair Hugger Model 505. 10 Q. And what is it? 11 A. You mean -- 12 Q. What is the title of the document, do you know? 13 A. Temperature management unit. 14 Q. Model 505. Is this the operator's manual? 15 A. Yes. 16 Q. What do you see on page 12? That was relevant to the 17 work you did here. 18 A. The last four lines, high 43 plus or minus 3C, medium 38 19 plus or minus 3C, low 32 plus or minus 3C, C means 20 centigrade. 21 Q. And is that the operating temperatures for the Bair 22 Hugger? 23 A. Right. 24 Q. And did you use this information in doing the work that 25 you did in this case?</p>
<p>875</p> <p>1 Q. And more precise than that would be? 2 A. LES. And the highest one is called DNS, direct 3 numerical simulation. 4 Q. And LES is what you did here? 5 A. For this project because it's the only way possible. 6 You can do RANS, and I think some people in papers like in 7 NIH, they use HANS, which is, again, I consider it rubbish. 8 Q. RANS? 9 A. Yes, for this kind of flow, yes. 10 Q. And why is that? 11 A. You remember we talked about boundary condition, RANS 12 will fail miserably near the walls of the room, near the 13 faces of the surgeons, near the table. When you get closer 14 to the wall of anything, RANS fails. 15 Q. It doesn't have the same kind of precision? 16 A. Well, it just gives you results. Wall region close to 17 an object is very crucial for turbulent flow because that's 18 a high sheer stress. 19 Q. Sheer like in an airplane. In your work from your 20 published paper, do you know how much heat is generated by 21 the Bair Hugger? 22 A. I just read the manuscript. It shows the 3M report or 23 manual is one kilowatt amount of power so the temperature 24 would be 38, 41, 43. 25 Q. Okay. I'm going to direct your attention to 1337, which</p>	<p>877</p> <p>1 A. Right. 2 MS. ZIMMERMAN: Plaintiffs are going to offer 3 1337. 4 MR. BLACKWELL: Your Honor, no objection to only 5 this provision. 6 MS. ZIMMERMAN: This page. Page 12 of 1337. 7 THE COURT: All right. Page 12 of 1337 is 8 received. 9 MR. BLACKWELL: Your Honor, the section labeled 10 temperature characteristics. 11 THE COURT: All right. The modification will be 12 made at the appropriate time. 13 MS. ZIMMERMAN: Okay. Permission to publish to 14 the jury. 15 THE COURT: Go ahead. 16 BY MS. ZIMMERMAN: 17 Q. There we go. Thank you. And is this the document that 18 you're looking at in front of you? 19 A. Correct. 20 Q. And does it outline the temperatures from the machine? 21 A. Yes. 22 Q. And which temperature did you use? 23 A. I think 41. I don't recall the exact figure but 41. 24 Q. And on the screen in front of you, does it show the 25 average temperatures at the end of the hose?</p>

	878		880
1 A. Yes.		1 of the drapes so uniformly coming to keep the mass flow rate	
2 Q. And that's 43 degrees Celsius; is that right?		2 the same, yes.	
3 A. Correct.		3 Q. Okay. So have you been asked to evaluate the effect	
4 Q. And it also says the air temperatures reaching the		4 that the Bair Hugger has on movement of particles in an	
5 patient are approximately two degrees centigrade lower than		5 operating room?	
6 the listed temperatures; is that right?		6 A. That was the main object of all the work, yes.	
7 A. Correct. We use 31 or 41.		7 Q. And are you prepared to explain to the ladies and	
8 Q. 41 degrees?		8 gentlemen of the jury what your work was with respect to the	
9 A. Yes.		9 Bair Hugger and the CFD you did?	
10 Q. Do you know if that's the same temperature that 3M used		10 A. Okay. So after --	
11 in doing their work on this matter?		11 Q. Could I stop you for just one second?	
12 A. I didn't look at their work. I didn't, yeah.		12 A. Yes.	
13 Q. Now, you modelled some draping in your work?		13 Q. Thank you. Do you have an opinion that you hold to a	
14 A. Correct.		14 reasonable degree of engineering certainty about the effect	
15 Q. And what import, if any, was the draping in the model		15 of the Bair Hugger machine on the disbursement of squame	
16 that you did?		16 size particles in an operating room?	
17 A. Okay. Before we did the work, we went with counsel to a		17 A. My opinion is based on our results.	
18 surgery room in Santa Monica, California, orthopedic surgery		18 Q. All right.	
19 hospital, and we asked the nurse to set up the Bair Hugger		19 A. I had no opinion before because of Navier-Stokes you	
20 blanket, drape, as she usually does in an operating room.		20 cannot guess about it. After we did the computations, I can	
21 And we took one of our colleague of the lawyer, she's a		21 say now, that, yes, the Bair Hugger causes squames to arise	
22 lawyer, and we asked her to lie down on the operating table		22 from the floor to higher elevation.	
23 covered with the Bair Hugger blanket, tied the things, and		23 Q. All right. And does that include over the operating	
24 covered the drape, and we asked the nurse to turn the Bair		24 room table?	
25 Hugger on. And we asked the lawyer on the bed whether		25 A. Correct.	
	879		881
1 there's air coming toward her face, and she said, no,		1 Q. And also to the surgical site?	
2 because she has contact lenses and if the hot air is coming		2 A. Say that again?	
3 to her eye, she would stop the thing. So she said no air		3 Q. Does your model also show squames reaching the surgical	
4 coming up. So we went around, there were other lawyers. We		4 site?	
5 looked at the airflow and all the air was coming at the		5 A. Yes.	
6 edges of the drape.		6 Q. So what did your LES model include in the operating	
7 Q. All right. Have you seen one of these before?		7 room? Are there squames?	
8 A. Correct.		8 A. Right. So after we did the geometry as shown by 3M, we	
9 Q. And what is this?		9 said the boundary condition from the drape, and in order to	
10 A. It's a blanket that should be connected to the Bair		10 give 3M the best case scenario I mean in their favor, we put	
11 Hugger with a hose.		11 the squames only on the floor, not anywhere in the room,	
12 Q. All right. And when you went to the operation, the		12 about one centimeter from the floor, so we put a layer	
13 operating room?		13 around the operating table with three million squames.	
14 A. Correct.		14 To give you an idea, each human being sheds 20	
15 Q. In Santa Monica?		15 million squames per hour. Think of that, that's a lot of	
16 A. Yes.		16 squames. And if you have five people, they shed hundred	
17 Q. Was there anything over this?		17 million squames per hour. To follow these squames, all of	
18 A. Yes, it's the same thing, yes.		18 them with the correct way we do it would be very expensive.	
19 Q. Was there anything placed on top of the blanket?		19 So we put only three million on the floor, only three	
20 A. The drape, it's a plastic drape. The nurse put it on.		20 million. And if you look from the top you look on the	
21 That's how they keep, yeah.		21 table, the operating table, the squames are taking a	
22 Q. All right. And were those part of the assumptions that		22 U-shape, means one side of the bed, one side of the bed, and	
23 you made as you were --		23 one side near the Bair Hugger. And we -- these are	
24 A. Right. So from what we saw, we know the flow rate		24 stagnant, they're not moving, and we turn the blower on. We	
25 coming from the blower, and we divided equally to the edge		25 follow them. Each one we follow, each individual squame,	

<p style="text-align: right;">882</p> <p>1 there's an equation to describe the motion of each squame, 2 and we followed that. It will give you a trajectory where 3 each -- so I give them a color code. I give green, red, and 4 green, red then yellow just to see the turbulent mixing how 5 it will affect, so you can see I think there's a video that 6 shows some of them go from the green side to the yellow side 7 or red side and so on, to monitor them.</p> <p>8 Q. Doctor, so the colors of the squame in your model, is 9 that just so that we can visualize?</p> <p>10 A. Absolutely. It's only for visualization. The color has 11 no effect on anything. Only the size of the squame, and 12 it's mass and density.</p> <p>13 Q. And so the super computer, what does it do with the 14 particle? I think you explained to the jury it calculates 15 where it moves?</p> <p>16 A. Right. So in addition to what we do with Navier-Stokes 17 equation to tell you the velocity and the pressure and the 18 temperature each point in the operating room, 19 simultaneously, you saw the motion of each of the three 20 million squame to see where they go.</p> <p>21 Q. So the computers are doing the Navier-Stokes equation 22 for each one of the three million squames?</p> <p>23 A. No, Navier-Stokes only for fluid motion. If you have 24 the -- squames have the density like liquid water, so think 25 of them as very tiny rain drops. Navier-Stokes only</p>	<p style="text-align: right;">884</p> <p>1 Q. And your work here in this case was done on the super 2 computer, right?</p> <p>3 A. Correct, yes.</p> <p>4 Q. Did you do a model with the Bair Hugger on and the Bair 5 Hugger off?</p> <p>6 A. That is essential. In order in science to see the 7 effect of something, you have to show without and with, then 8 you see the difference.</p> <p>9 Q. And what, if anything, did you learn from doing the CFD 10 LES with the Bair Hugger off?</p> <p>11 A. With the Bair Hugger off, the airflow from the ceiling 12 scavenges everything in front of it, and the flow exits from 13 the floor, exit grilles near the floor.</p> <p>14 Q. So did you see that the airflow was effective?</p> <p>15 A. Yeah, we can follow, yeah, we can follow, yeah, uh-huh.</p> <p>16 Q. Okay. Do you recall what mass flow rate you used in 17 solving these equations?</p> <p>18 A. Mass flow rate from the ceiling or from the Bair Hugger?</p> <p>19 There are two.</p> <p>20 Q. From the Bair Hugger?</p> <p>21 A. I don't recall. It is given somewhere in a table. We 22 use that from Bair Hugger, yes.</p> <p>23 Q. Do you know if it was from a 3M document?</p> <p>24 A. Yes. I recall I think we used a little bit lower than 25 what was written by few percent.</p>
<p style="text-align: right;">883</p> <p>1 applies to a continuum fluid means the molecules 22 to the 2 10 in one centimeter cube. That's just one fluid.</p> <p>3 Particles are foreign objects like oranges. They have their 4 own equation, which took 150 years to develop, so we solved 5 that equation individually to each squame.</p> <p>6 Q. So you solved that equation for each one of the three 7 million squames?</p> <p>8 A. We saw that every microsecond three million. That's why 9 you need a super computer. You can't do it on a laptop or 10 some other machine.</p> <p>11 Q. How long did it take the super computer to this?</p> <p>12 A. If the machine is running without interruption, it takes 13 about 10, 12 hours. It will take 200 years if you want to 14 do it in other machine.</p> <p>15 Q. Okay.</p> <p>16 A. Yeah.</p> <p>17 Q. Which super computer did you use?</p> <p>18 A. The one in University of Texas at Austin.</p> <p>19 Q. All right. Can anybody use the --</p> <p>20 A. No, no, in order to have access to these machines, you 21 have to write a proposal to a National Science Foundation to 22 tell them I would like to solve this problem. It will be a 23 peer reviewed by five people around the country, again, 24 confidentially, and when they see that your work deserves to 25 use a super computer, they will let you do that. Okay.</p>	<p style="text-align: right;">885</p> <p>1 Q. Do you know if you used the same mass flow rate as 3M's 2 witness?</p> <p>3 A. Again, if you're referring to the video of 3M, they had 4 a table that would probably use the same, yes.</p> <p>5 Q. And did the LES CFD that you did on the Model 505 6 generate videos?</p> <p>7 A. Correct.</p> <p>8 Q. And is that something that this super computers 9 typically do when you do this kind of work?</p> <p>10 A. Not typically, but you ask them to do it like after you, 11 after you do the simulation, you save certain parts in a 12 given time period, you store them, and then you run a video 13 generating code using your data. So the video is -- 14 remember, when you have hundreds of millions of points in 15 the mesh, the mesh will have tens of million, hundreds of 16 million, you cannot read the results at each point. It's 17 impossible to read in time every microsecond of flow 18 changing, so the best way to visualize that is to create a 19 video to tell you how everything is moving, yes.</p> <p>20 Q. And is that something that you do with some regularity 21 in your work?</p> <p>22 A. Right, right. That's the way to do for DNS or LES 23 because the amount of data is huge, yes.</p> <p>24 Q. All right. And do you know was the super computers that 25 you worked on or that you used for this, were they</p>

<p style="text-align: right;">890</p> <p>1 Q. All right. What impact, if any, would there be if the 2 people were moving? 3 A. It would be much worse. I mean, I summarize first, all 4 the simulation we did, we did everything in the simulation 5 to provide the best case scenario for 3M, not for us. I 6 wanted the best case scenario. I wanted to see, put 7 everything on the floor, because in general, in a operating 8 room, the squames are everywhere. We could have put them 9 one meter high, two meter, we put them near the ceiling, 10 then they will drop, but we did not do that. We put, again, 11 best case scenario for 3M. So these came from the floor up 12 only if the Bair Hugger is on, yeah.</p> <p>13 Q. Doctor, as you were preparing your work in this case, 14 did you review an article by Dr. Memarzadeh? Does that name 15 familiar?</p> <p>16 A. A long time ago, just somebody told me there is a person 17 at NIH who did something and related. I looked at it and I 18 think he was using RANS, R-A-N-S, which, as I described 19 earlier, is the lowest level of simulation, means 20 untrustworthy for this load. You can use RANS for a garden 21 hose, that's okay, but you use it for this, that's bad, bad 22 idea.</p> <p>23 Q. Doctor, do you remember what size particles 24 Dr. Memarzadeh --</p> <p>25 A. Ten microns.</p>	<p style="text-align: right;">892</p> <p>1 A. I don't remember, maybe 3,000. It could be written here 2 somewhere. 3 Q. 4,000 sound right? 4 A. 4,000, okay.</p> <p>5 MR. BLACKWELL: Objection, Your Honor. Leading. 6 THE COURT: It is. 7 MS. ZIMMERMAN: All right.</p> <p>8 BY MS. ZIMMERMAN:</p> <p>9 Q. The fifth line down in the first full paragraph. 10 A. Okay. Yes.</p> <p>11 Q. And I'm going to direct your attention about midway 12 through the paragraph. 13 A. Yeah. 14 Q. And your paper says, it's the sentence starts out they. 15 Do you see that? 16 A. Yeah, they, the first word in the sentence they, upper 17 case they. 18 Q. Could you read that to the ladies and gentlemen of the 19 jury? 20 A. They showed that roughly 2 percent to 5 percent of 21 particles reach the surgical site, and in italics, provided 22 they are originated very close, about 1.3 centimeter above 23 the site, yes. 24 Q. Okay. And your particles started where? 25 A. On the floor, yeah. We avoided anything, yeah.</p>
<p style="text-align: right;">891</p> <p>1 Q. The same size you used? 2 A. Yes. 3 Q. And he used the RANS model. Is that right? 4 A. Yes. 5 Q. Did Dr. Memarzadeh include a drape in his -- 6 A. No. 7 Q. And what impact, if any, does that have on the results? 8 A. Well, we tried to put everything in the operating room 9 as I saw it by myself in the Santa Monica operating room. 10 That's the nurse told us this is how we do orthopedic 11 surgery, so I followed that. 12 Q. Do you know, did Dr. Memarzadeh, did he conclude that 13 particles reached the surgical site as well? 14 A. I could not hear what you said. 15 Q. I'm sorry, I'm not speaking into the microphone. 16 A. Oh, okay. Okay. 17 Q. Let me direct you, the book in front of you, Plaintiffs' 18 Exhibit 1419, page 3. 19 A. Yes. 20 Q. And the first full paragraph, did you start out 21 discussing Dr. Memarzadeh's work? 22 A. Correct. 23 Q. Do you know how -- he used a RANS model. Is that right? 24 A. Correct. 25 Q. Do you know how many particles he modeled?</p>	<p style="text-align: right;">893</p> <p>1 Q. Did Dr. Memarzadeh's group use a drape? 2 A. I don't think so, no. 3 Q. Okay. And why -- why might a drape matter? 4 A. Again, go back to Santa Monica hospital, we had to do 5 the conditions in a operating room identical to what happens 6 in reality when you have a surgery, so I did not omit 7 anything, except some insignificant machines, computers and 8 things which are not really important. 9 Q. Okay. Tell me about that, Doctor. You -- have you seen 10 pictures of the operating room that was where Mr. Gareis's 11 surgery took place? 12 A. I think the during the deposition the counsel of 3M 13 showed me photographs of a operating room called Providence. 14 I don't know what it is. But he showed me the machines and 15 yes. 16 Q. Okay. And, in your model, did you include a patient? 17 A. Include a patient? 18 Q. Yes. 19 A. Yes. 20 Q. Did -- what about a surgical team? 21 A. We have four, four surgical team people. 22 Q. What other equipment did you use in your model? 23 A. Well, the Bair Hugger surgical masks, and that's it. 24 Q. There have been some questions to other witnesses about 25 other devices used in that operating room. Do you know what</p>

	894		896
1 a electrocautery device is?		1 to process the data. You need highly qualified people. And	
2 A. Say it again, please.		2 this will be the nearest thing to an LES. Then you can go.	
3 Q. Yes. Do you know what a electrocautery device is?		3 It costs minimum \$2 million, in addition to having access to	
4 A. Yes. Yes, I do.		4 operating room for two months. Nobody should enter in	
5 Q. Okay. And is that used throughout the course of a		5 because the optical equipment has to be set up. In the	
6 operation?		6 absence of this, then you have to go back to your code and	
7 A. No, it's a intermittent device. You use it for a few		7 see if it was validated in other flows, and that what's we	
8 seconds to close a wound and that's it.		8 did.	
9 Q. And what import, if any, is the fact that the device is		9 Q. Okay. So let me ask you, so did you do -- did you use a	
10 used intermittently, what impact does that have on the		10 PIV to validate your work here?	
11 opinions that you have in this case?		11 A. I did not. You need very specialized people. The best	
12 A. Well, in our project, we are interested in fact of hot		12 person I know, there are two or three people in the company,	
13 air relieving the Bair Hugger and the drape on the motion of		13 one at Caltech, one at Arizona, yeah, so you have to get	
14 squames in the room. And a machine like you just mentioned		14 those people with their post docs and Ph.D. and pay them	
15 had no effect or insignificant effect on that behavior.		15 quite a bit of money and in addition to buying	
16 Q. All right. Do you -- do you know how many watts, for		16 four-dimensional cameras and then you can do that.	
17 example, an electrocautery device generates?		17 Q. Okay. So you didn't do PIV here. Is your work still	
18 A. I think about maybe 300-watt maybe or 300 to 500,		19 validated?	
19 depends, yeah.		19 A. Absolutely. Because that code was validated over	
20 Q. Do you know about anesthesia, how many watts the		20 15 years, at least 15 years at Stanford University where the	
21 anesthesia machine emits?		21 code was created. And that goes through testing like	
22 A. Yeah, they're all about a hundred watts, much lower than		22 testing plain, simple flows, more difficult, until you do	
23 the hair dryer in your bathroom, much lower, and		23 something like the flow inside the shift engine combustor	
24 intermittently used.		24 for Pratt & Whitney or Rolls-Royce you do that. After you	
25 Q. And they are more or less watts than the Bair Hugger		25 do all this means you solve a energy equation and more and	
	895		897
1 machine?		1 other equations or chemistry, then you know your code is	
2 A. They're all below the Bair Hugger machine, yes.		2 fine, then you can use it for simpler flow like this one.	
3 Q. You have another video I think from a different angle?		3 The operating rooms are much simpler flow than the flow	
4 A. Yes.		4 inside a combustion chamber of a jet engine that you fly	
5 Q. Can you explain to the ladies and gentlemen of the jury		5 because that combustion chamber is very liquid filled, in	
6 what they're going to see in this video?		6 different sizes, and much higher temperature, 2,000 degrees	
7 A. It's a close-up on the previous video to show when the		7 centigrade, and swirling, highly complex. If the code can	
8 Bair Hugger is on, how the different color squames would		8 predict that to satisfaction of the manufacturer of the jet	
9 rise or where would they go, yes.		9 engine, then when you go to an operating room, then you know	
10 Q. How do you validate the work that you do? How is CFD		10 it's fine, yeah.	
11 validated?		11 Q. So if the code has been validated for more complicated	
12 A. That's a good question. So if there is a simple flow,		12 problems --	
13 you can run an experiment using noninvasive -- I'll go back		13 A. Yes.	
14 a little bit. If you want to provide measurement in a		14 Q. -- it's also valid for --	
15 turbulent flow, you cannot put your hand in it because that		15 A. Yes. Yes.	
16 would be invasive to the flow. You cannot do that.		16 Q. -- less complicated problems?	
17 Q. If you reached your hand in, it would interrupt the		17 MR. BLACKWELL: Objection, Your Honor.	
18 results?		18 THE WITNESS: Remember validation takes many	
19 A. Yeah, putting whatever device was suggested by other		19 years. First you do very simple flow, LES and a pi flow,	
20 people, you cannot do that, so it has to be noninvasive,		20 then a channel flow, then a cavity flow. You can do, there	
21 means you have to use optical devices, laser beams. And you		21 are many scenarios which I think I summarized in my year ago	
22 can spend a long time to be trained of how to use it. You		22 to I think it was sent to the counsel of 3M. So validation,	
23 have to at least a Ph.D., at least, and use these optical 3D		23 it's published in peer-reviewed papers. Stanford have the	
24 like PIV particle image velocimetry and you need access to		24 best group in the world. It's called Center for Turbulence	
25 that operating room for two months, at least, and one month		25 Research, the whole thing is called Center for Turbulence	

	946		948
1 A. Okay. The temperature of the -- for a steady state, the 2 temperature leaving the exit of the hose is the same as 3 leaving the holes after being around for a long time, not at 4 the beginning. The beginning would be a difference between 5 this one and the exit of the hose and the exit of the air, 6 but if you ran it for how far, the temperature, at least 7 the -- the hole is very close to the end of that would be 8 the same, no difference.		1 Q. No, no, I'm not trying to make up anything. 2 A. All right. 3 Q. Sir, if pull up defense 966. Oh, I'm sorry. And here, 4 sir, is where you say, the following data will be provided 5 by Gabriel. 6 A. Right. 7 Q. And Gabriel is Gabriel Assaad, isn't it? 8 A. He's a gentleman sitting there, yes. 9 Q. He's a gentleman too. 10 A. Yes, yes. 11 Q. Gabriel Assaad, and that's one of the plaintiff's 12 lawyers?	
9 Q. And you were then looking to take the temperature, where 10 do you believe the air exited at the bottom of the drape 11 that you talked about?		13 A. Right. And I know you're using terminology that I'm not 14 very familiar with, but yes, he is the gentleman sitting 15 there, yes.	
12 A. That's computed, not assumed.		16 Q. Okay. So if you look here what's on the screen, these 17 six items that I just had up on the chart also --	
13 Q. All right.		18 A. Yes.	
14 A. It's computed.		19 Q. -- are the ones you expected --	
15 Q. And so that would have been a different temperature from 16 the temperature at the end of the hose, right?		20 A. Yes.	
17 A. Yes. Yes. And the report showed that.		21 Q. -- to be provided to you by the plaintiffs' lawyers?	
18 Q. Let's go back to our list. In any event, you wanted to 19 know the air inflow rate to the Bair Hugger?		22 A. You can see how careful I am, I needed all this at the 23 beginning of the project. I wanted this information. And 24 after that we had to go to Santa Monica to provide some of 25 the answers to these questions.	
20 A. Yes.	947		949
21 Q. And the temperature of the air leaving the blanket?		1 Q. Dr. Elghobashi, once the lawyers who are suing 3M gave 2 you this information, isn't it true that you didn't do 3 anything yourself to independently verify that what you were 4 getting was accurate? Is that true?	
22 A. Correct.		5 A. Yes, as I said repeatedly, I went by myself to 6 Santa Monica Hospital, spent a day there with nurses to 7 measure everything. So what you mean I did not prove, I 8 mean, I am the one who asked to go to hospital. They took 9 them a long time to find a free hospital to interrupt. I am 10 the one who requested that.	
23 Q. And you wanted a drawing of the blanket and the 24 locations of the drape edges near the floor, true?		11 Q. Well, let's take, for example, look at No. 2 on this 12 list, the dimensions and locations of the inlet and exit air 13 groups?	
25 A. Can I ask a question, are you showing me a table that I		14 A. Yes.	
1 created? I don't know where the table, is this my table?		15 Q. So you had the exit air grilles down at the floor, true?	
2 Q. I don't know that it's your table, but I think these are 3 things that you thought were key and important measurements, 4 aren't they?		16 A. Right.	
5 A. Right. That means I probably have asked somebody to 6 provide me at the beginning of the project I think.		17 Q. And you were expecting to get information about the exit 18 air grilles?	
7 Q. But you did want a drawing of the blanket and the 8 locations of the drape edges near the floor. You wanted 9 this last one too?		19 A. Right.	
10 A. Absolutely, yeah, yeah, yes.		20 Q. From these lawyers, right?	
11 Q. And so my next question, which you may have anticipated, 12 is who would have supplied these measurements that you 13 wanted?		21 A. Right, yes.	
14 A. So eventually we had to go to Santa Monica to do that. 15 That we -- the reason for going to Santa Monica Hospital is 16 to provide this information. That what the main reason we 17 went to an operating room, yes.		22 Q. Did you do anything to verify that the exit air grilles 23 were, in fact, at the bottom of the floor as apparently had 24 been represented to you?	
18 Q. Isn't it true that every single one of these key and 19 important measurements were provided by the plaintiffs' 20 lawyers? Every one of them? Isn't that true, sir?		25 A. Sir --	
21 A. Okay, they gave me the drawing of the blanket from 3M, 22 and the temperature I got it from the hose from your manual, 23 and the airflow rate for the Bair Hugger, from the manual. 24 They may have given me the manual to look at this. If you 25 want to say they gave it to me, that's fine.			

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1	Q. Just yes or no, sir.	1	very small, computers in operating room has nothing, all
2	A. I disagree. Your question is not like that. You're	2	other devices that use intermittently for few seconds or
3	saying that the dimension of the grille, the four grilles in	3	minute will have no impact, in addition, any electric device
4	the floor taken from 3M geometry, the ten grilles in the	4	that generates heat with a fan will create its own plume.
5	ceiling, these were taken from either from 3M geometry or	5	If you have many plumes in the room, it will be the worst
6	Rochester, when you go to a operating room, we visit all of	6	case scenario for 3M, so I did not. I wanted to have a pure
7	them, they have different grilles like the one you	7	operating room that you not raise any issue about it, trust
8	mentioned, Providence, so you want me to simulate all	8	me.
9	operating rooms in the world?	9	Q. Do you recall what my question was, Dr. Elghobashi?
10	Q. No, sir, I just want to know when you received	10	A. I don't recall the question.
11	information from the lawyers when you did any homework or	11	Q. It's true, isn't it, that you're not able to tell me or
12	research yourself to --	12	the jury or anyone what the make or model or any of the
13	A. A lot.	13	details or specifics were for any piece of equipment that
14	Q. -- independently verify?	14	was, in fact, in the operating room for Mr. Gareis on the
15	A. I did a lot.	15	day of his surgery on November 9th, 2010, that's true, isn't
16	Q. What did you do, for example, to --	16	it?
17	A. Looking at geometries and ventilation system of -- by	17	A. I totally agree with you.
18	HVAC people. There were journals. I spent many, many hours	18	MR. BLACKWELL: I'm going to switch gears, Your
19	trying to get that, finally decided that all operating rooms	19	Honor.
20	have different inlet, outlet, like the one in Providence, so	20	THE COURT: Actually, we'll take lunch break and
21	I took the best case scenario for 3M. All the outlets on	21	resume at 2 o'clock.
22	the floor, that's the best case. If you lose outlet, you	22	(1:07 p.m.)
23	will have more squames out, trust me.	23	* * * * *
24	Q. You were asking, sir, for the locations of inlet and	24	
25	exit air grilles --	25	
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1	A. Yes.	1	PROCEEDINGS
2	Q. -- as pertained to Mr. Gareis in the hospital in this	2	(2:09 p.m.)
3	case? What did you do to verify that the information that	3	THE COURT: Please be seated. And Dr. Elghobashi,
4	you got was accurate?	4	you're still under oath from this morning. And Mr.
5	A. Mr. Goss showed me the grille location in Providence	5	Blackwell is going to resume his questioning, whenever he's
6	operating room, and I told him, and I repeat again, the	6	ready. Are you ready?
7	location of the grille on the wall at the higher elevations	7	THE WITNESS: Yes.
8	of the floor increases, enhances the dispersion of squame	8	THE COURT: All right.
9	toward the table because that allowed the plume of the 505	9	BY MR. BLACKWELL:
10	to rise higher. If the grille were down, air would --	10	Q. Good afternoon again, Dr. Elghobashi.
11	incoming air would push the heated air down. If you -- if	11	A. Good afternoon.
12	you put all the outlet grilles higher, you would have a much	12	Q. I hope you had a nice lunch.
13	worse operating room.	13	A. Thank you.
14	Q. So I think I've gotten about the best answer I'm going	14	Q. I want to go back to the testing you did of the Santa
15	to get, so I'm going to move on and ask you another	15	Monica that you talked to us a little bit about.
16	question.	16	A. Yes.
17	A. Okay. All right. Good.	17	Q. And I believe it's true that you had never before seen a
18	Q. So you made the statement awhile ago when the other	18	Bair Hugger set up in an operating room at the time of the
19	lawyer was standing here that all the other machines in the	19	experimentation you did out in Santa Monica; is that right?
20	operating room had less watts than the Bair Hugger machine.	20	A. Correct.
21	Who told you that?	21	Q. So is it true then that the persons who actually set up
22	A. I looked in it the web about the different machines in a	22	that operating room and arranged the whole thing were,
23	operating room, including an anesthesia machine, the	23	again, these lawyers; is that right?
24	cauterizing machine, the all of that, computer, for example,	24	A. Could you repeat the question again, please?
25	the fan of any computer produce like ten watt or something,	25	Q. The persons who set up the visit to the operating room

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1 Q. So let's bring this back to the operating room number 4 2 at Providence Hospital Northeast in Columbia, South 3 Carolina, where the surgery took place on November 9, 2010. 4 Now, were you aware that there was an opportunity for 5 experts like yourself to come out to the actual operating 6 room Mr. Gareis had been invited to take your own measurements. 7 Did you know that? 8 A. I will repeat what you told me, just to make sure I 9 understood. You said I could have gone to whatever this 10 other hospital is and take measurements and I said earlier I 11 don't trust in taking measurements the way you propose so 12 why would I go to place to do something that is illogical to 13 me? It doesn't make sense. 14 Q. Let me ask my question again because I don't want to 15 argue with you. 16 A. Okay. 17 Q. I just want to know whether you were aware that there 18 was an opportunity for an expert like yourself to come out 19 to the hospital where the surgery took place and either take 20 measurements or have measurements taken. Did you know that? 21 A. I have not known that. 22 Q. So to the extent there was a meeting set up for that 23 purpose, is it fair to say that you weren't invited to the 24 meeting as far as you know? 25 A. I was not invited to a meeting in the Carolinas.		1 Q. Okay. And lines 22 through 25. 2 A. I do. 3 Q. And do you see where the question is asked -- where you 4 ask -- 5 A. Yes. 6 Q. -- how come they didn't show me these pictures before 7 today? 8 A. Right. 9 Q. What did your lawyer say? Would you read that for the 10 ladies and gentlemen of the jury? 11 A. Because they are irrelevant. 12 Q. So when you asked how come you didn't see the pictures 13 before today, it was the same lawyers who are telling you 14 that the pictures that show the actual operating room are 15 irrelevant, that's what they said? 16 A. That's what's written here, yes. 17 Q. And that's what you heard? 18 A. I don't remember but it's written, means I heard it, 19 yes. 20 Q. So in any event, had Mr. Goss or 3M not shown you the 21 photographs of the operating room, for all you know you'd 22 never have seen them, right? 23 A. Correct. 24 Q. Now, going to another subject, Dr. Elghobashi. The jury 25 has heard some references already that relate to the	
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1 Q. Now, when you were finally able to see the actual 2 photographs of operating room number 4, and you said 3 Mr. Goss showed them to you? 4 A. Yes. 5 Q. There is Mr. Goss? 6 A. I met him in the morning. 7 Q. And he showed them to you, and at the time he showed you 8 those photographs, didn't you ask the question how come 9 these photographs weren't shown to me before today. Isn't 10 that what you asked? 11 A. My memory is not very good, but if it was written that I 12 said that, then I trust you. I cannot remember. I mean I 13 have so many things. 14 Q. I'm okay, I'll do trust to verify. So if you could look 15 in your big binder we have up there. 16 A. Oh. 17 Q. And look your deposition for February 10th of 2018. 18 A. Okay. I have it. 19 Q. And then go to page 226 and lines 22 through 25 on 20 page 226? 21 A. I have -- I have page -- the page has four pages. The 22 one page has four squares, right? 23 Q. If you look at the square that has the 226 in the 24 corner. 25 A. Okay, I have it.		1 movement of personnel and in and out of the operating room and 2 the significance of that. Do you understand that the 3 movement of personnel in and out of the operating room is an 4 important risk factor for surgical infections? Do you know 5 one way or the other? 6 A. I'm not a medical doctor. 7 Q. Now, I think you told us before that none of the 8 personnel that you had depicted in your CFD move? 9 A. Correct. 10 Q. If the -- at least assume for purposes of my question 11 that the international consensus of orthopedic surgeons has 12 a statement, persons in the operating room are a major 13 source of bacterial load and shed bacterial particulates. 14 These particulates circulate through the operating room via 15 air currents. Movements of personnel and objects, including 16 operating room equipment and opening and closing doors, can 17 generate significantly marked air currents and increase the 18 probability of bacteria being deposited in the surgical 19 site. So I take it given your answer that you are not a 20 medical doctor, then you don't have any basis to disagree 21 with the international consensus of orthopedic surgeon on 22 the significance of the movement of personnel and object in 23 the operating room? 24 A. I agree on parts of this that does not mention infection. If you open the door or let the people move, you	

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1 will enhance the spreading of squames. I'm not talking
 2 about infection. So that's why I said all our computations
 3 were done as the best case scenario for 3M not our side.
 4 Q. You keep repeating that. Are you --
 5 A. Yes, I do.
 6 Q. -- suggesting --
 7 A. I do, I do.
 8 Q. May I finish, please, sir? Are you suggesting to the
 9 jury that you are being paid over \$250,000 to help 3M, are
 10 you trying to suggest that?
 11 A. The science, what the science I perform to prove to show
 12 these results, I could have picked moving people easily. I
 13 could have opened/closed the door and the squames would have
 14 been risen at a much higher rate than what I did, so I did
 15 the one -- you mentioned the money. Don't mention the
 16 money. I don't care about the 250, that's just nothing.
 17 Q. You don't care, it's nothing?
 18 A. Absolutely nothing for because it's paid to students.
 19 Q. Dr. Elghobashi, if what the jury wants to get is an
 20 accurate picture of the nature of squames or particles or
 21 bacteria.
 22 A. Yes.
 23 Q. Taking into account all of the factors that may have
 24 contributed to it in the operating room, we can agree that
 25 your CFD does not depict that, true?

1 Q. If the jury wants to understand all of the factors in
 2 the operating room that would contribute to the movement or
 3 air currents and/or the creation of squames or particles,
 4 Mr. Gareis's operating room, your CFD does not take into
 5 account all of the factors that would have contributed to
 6 the movement of air currents in the operating room. That's
 7 a true statement, isn't it?
 8 A. I disagree. And you want me to explain to you why, I
 9 will do it. I disagree with that statement, yes, I do.
 10 Q. Well, let me ask you then this way. If you say you
 11 disagree and you took into account all of the factors, isn't
 12 it true that in no respect whatsoever did you attribute any
 13 value to the fact that the doors to that operating room were
 14 opened and closed at least six times during the surgery of
 15 Mr. Gareis on November 9, 2010, you didn't factor in even
 16 one of them, did you, sir?
 17 A. I did not account for any door closing or opening.
 18 Q. Thank you. You answered my question.
 19 A. Okay.
 20 Q. Isn't it true that to the extent there's other equipment
 21 in the operating room that generates heat or blows air, you
 22 included not a single one of them in your CFD. Isn't that
 23 also true?
 24 A. It is true but irrelevant.
 25 Q. That may be your opinion. I'm just trying to understand

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1 A. I repeat again. If we allowed the people to move and
 2 the doors to open and close, the Bair Hugger effect would
 3 have been enhanced in spreading squames. So we did it such
 4 that just to isolate the effect of the Bair Hugger, that's
 5 how we do science.
 6 Q. With all due respect, sir, you're not answering my
 7 question. If the jury wants to understand all of the
 8 factors in the operating room that might affect the air
 9 currents, the movement of squames or particles or bacteria,
 10 your CFD does not encompass or include all of the factors
 11 that would contribute to air movement occurrence in the
 12 operating room. Is that true?
 13 MS. ZIMMERMAN: Objection, Your Honor. Asked and
 14 answered.

15 THE COURT: Overruled.

16 BY MR. BLACKWELL:

17 Q. Is it true, sir?
 18 A. I answered my answer which is the correct answer for me.
 19 I cannot answer any more. What do you want me to do?
 20 Q. I would like you to tell me if it's true or not true,
 21 sir?
 22 A. Which is what is true and not, could you repeat it
 23 again?
 24 Q. I will try one more time.
 25 A. Yes, please.

1 what you did and what you considered. Isn't it also true,
 2 even though you said you were putting together the best case
 3 for 3M, that the patient that you had modelled in your CFD
 4 was a patient that had zero bacteria on his or her own body.
 5 Isn't that true?
 6 A. Do you mean I made sure that our patient in the
 7 simulation is not sick?
 8 Q. No, that's not what I meant.
 9 A. If you have bacteria on something means it's not right.
 10 I did not -- I took a clean patient.
 11 Q. All right. So a clean patient, you meant a patient that
 12 had no bacteria is what you took, true?
 13 A. We do not account for bacteria because they are much
 14 smaller than the smallest turbine scale.
 15 Q. Sir, I'm trying to understand what you assumed. So when
 16 you say that you took a patient that was cleaned or whatever
 17 word you used, you presume to have a patient in your CFD
 18 that contained no bacteria on his or her skin, that's a true
 19 statement, isn't it?
 20 A. I disagree. The simulation does not account for
 21 bacteria at all, whether patient or floor or medical stuff,
 22 so there is no place to put bacteria in because bacteria is
 23 much smaller than the particle, the squames.
 24 Q. All right. So fairness to your point, if there is no
 25 bacteria taken into account, that means there would have

<p align="center">UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA</p> <p>-----</p> <p>Louis Gareis and Lillian Gareis, Plaintiff, v. 3M Company and Arizant Healthcare, Inc., Defendant.</p> <p>) VOLUME IX) File No. 16-CV-4187) (JNE/FLN)) May 25, 2018) Minneapolis, Minnesota) Courtroom 12W) 9:32 a.m.) -----</p> <p>BEFORE THE HONORABLE JOAN N. ERICKSEN UNITED STATES DISTRICT COURT JUDGE</p> <p>(JURY TRIAL - VOLUME IX)</p> <p>APPEARANCES</p> <p>FOR THE PLAINTIFFS:</p> <p>MESHBESHER & SPENCE Genevieve M. Zimmerman 1616 Park Avenue Minneapolis, MN 55404</p> <p>CIRESI CONLIN Michael Ciresi Jan Conlin 225 South 6th Street Suite 4600 Minneapolis, MN</p> <p>KASTER LYNCH FARRAR & BALL, LLP Kyle Farrar 1010 Lamar, Suite 1600 Houston, TX 77002</p> <p>KENNEDY HODGES, LLP Gabriel Assaad 4409 Montrose Blvd Suite 200 Houston, TX 77006</p> <p>FOR THE DEFENDANTS 3M: BLACKWELL BURKE P.A. Jerry Blackwell Ben Hulse Mary Young Corey Gordon Peter Goss 431 South Seventh Street Suite 2500 Minneapolis, MN 55415</p> <p>MITCHELL WILLIAMS Lyn Pruitt 425 West Capitol Avenue Suite 1800 Little Rock, AR 72201</p> <p>COURT REPORTERS: MARIA V. WEINBECK, RMR-FCRR RENEE A. ROGGE, RMR-CRR 1005 U.S. Courthouse 300 South Fourth Street Minneapolis, Minnesota 55415</p> <p>Proceedings recorded by mechanical stenography; transcript produced by computer.</p>	<p align="right">1562</p> <p align="right">1564</p> <p>1</p> <p align="center">PROCEEDINGS</p> <p>(9:32 a.m.)</p> <p>THE COURT: Good morning. Welcome back. Please be seated. Good morning.</p> <p>MR. GOSS: Good morning, Your Honor. Your Honor, defendants call Michael Keen as our next witness.</p> <p>(Witness sworn.)</p> <p>THE COURT: Please take the witness stand, which is right there, and once you're comfortable, state your full name, spelling your last for the record.</p> <p>THE WITNESS: Good morning. My name is Michael Keen.</p> <p>THE COURT: Spell your last.</p> <p>THE WITNESS: Oh, sorry. K-E-E-N.</p> <p align="center">DIRECT EXAMINATION</p> <p>BY MR. GOSS:</p> <p>Q. Good morning, Mr. Keen. My name is Peter Goss. I'm one of the lawyers for 3M, and I'm going to have a few questions for you this morning. Mr. Keen, where are you from?</p> <p>A. I'm from Toronto, Ontario, Canada.</p> <p>Q. Okay. And Brett, can we bring up slide number 1, please?</p> <p>Toronto, is that north or south of here?</p> <p>A. Ironically, it's actually southeast of here.</p> <p>Q. Okay. Well, thanks for coming up from Canada. Where do you work, Mr. Keen?</p> <p>A. I work at a group of hospitals in Toronto, St. Michael's, St. Joe's, and Providence Health Care.</p> <p>Q. And over the course of your education, training, and experience, have you developed expertise in hospital engineering?</p> <p>A. Yes, I have.</p> <p>Q. And does that include heating, ventilation, and air conditioning, or what we might refer to as HVAC, in hospitals and health care facilities?</p> <p>A. Yes, it does.</p> <p>Q. All right. Brett, could you pull up slide 2, please?</p> <p>I'd like to review your education briefly. You were an undergraduate at the University of Waterloo. Is that in Ontario, Canada?</p> <p>A. It is Ontario.</p> <p>Q. And you received a bachelor of science in mechanical engineering. Is that right?</p> <p>A. Bachelor of applied science in mechanical engineering, yes.</p> <p>Q. Thank you. And then you went on to pursue an MBA at Queens University, also in Ontario; is that right?</p> <p>A. Yes, that's right.</p> <p>Q. Were you working during the time that you received your MBA?</p>
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1 Q. Okay. And what does the standard say? You don't have 2 to read it, but just explain to the jury what the standard 3 says for the location of the diffusers.		1 And we call that space where the air vents are to be over 2 that table sort of the one foot around the perimeter of the 3 operating room table that it should occupy that 70 percent 4 of the ceiling space. So here's it's a simplified view, you 5 can see it's -- they have the vents that are in the ceiling, 6 and the air there is being blown down towards the operating 7 room table and once it gets there, it's washed away to 8 sides.
4 A. Okay. The location of the diffusers that calls for in 5 the standard that they should be concentrated to provide 6 airflow over the patient and the surgical table which are 7 located in the center of the room.		9 You'll notice as well on the two sides here in the 10 corner, there are exhaust vents, so this is where the air 11 gets exhausted from the room, so effectively the airflow 12 pattern that we're trying to achieve is to have the air 13 supplied from the center of the room over the top of the 14 patient and the operating room table over the staff that are 15 there and washed away to the outsides and then exhausted 16 from the corners.
8 Q. Okay. And then we've got -- that's part A. And then 9 subpart B, could you go to the next slide, Brett?		17 Q. Now, I want to ask you what's shown on the sides, the 18 left and right sides of the drawing. What are we seeing 19 there?
10 Okay. And then what does subpart B say about the 11 area over the operating table?		20 A. So the air that comes in initially, the idea is to try 21 and achieve a unidirectional sort of flow downwards so that 22 air is going down into the room as opposed to mixing as soon 23 as it gets there. Once it starts to hit things in the room, 24 the table, the patient, and it hits the floor, it starts to 25 go out to the sides and you can see where it starts to get a
12 A. It says that it references the fact that there are other 13 things other than the air vents in the ceiling such as the 14 operating room lights, articulating arms, gas columns that 15 might be in the ceiling sprinkler heads, and so it says that 16 over this primary diffuser array, so this section of vents 17 in the center of the room over the patient and the operating 18 table, that no more than 30 percent of that space should be 19 for these other things. 70 percent of that space should be 20 just for the air vents themselves.		
21 Q. Okay. And Brett, can we go back to the previous slide, 22 please?		
23 And does part A also specify an airflow velocity 24 for the diffusers over the table?		
25 A. Yes, it does. It calls for an average velocity range of	1579	
1 25 to 35 feet per minute.		1581
2 Q. And how would you characterize that velocity?		1 little turbulence on the sides there and starts to mix 2 around, that's what happens on the sides.
3 A. I would say that's a very -- what we call a low 4 velocity.		3 Q. Okay. Is there any way to prevent turbulence in the 4 operating room with an HVAC system?
5 Q. Okay. Now, did you prepare a report for your work in 6 this case?		5 A. No, not completely.
7 A. Yes, I did.		6 Q. Now, would it be accurate to describe this pattern of 7 airflow over the surgical table as a force field?
8 Q. And in your report did you cite a drawing that relates 9 to the airflow patterns created by an ASHRAE 170 compliance		8 A. No, I wouldn't call it a force field.
10 system?		9 Q. How would you characterize it?
11 A. Yes, I did.		10 A. It's more like a waterfall coming down.
12 Q. And would that aid your testimony to the jury this 13 morning?		11 Q. Okay. Would it feel like a waterfall if you were to go 12 to Minnehaha Falls and stand under it?
14 A. Yes, that would be a helpful illustration.		13 A. No, no, it's not that strong. I mean, again, I 14 mentioned it's a low velocity of air so it's probably more 15 like a soft rain or drizzle that's coming down if I had used 16 the waterfall analogy, but it's a low velocity of air that's 17 wafting over.
15 Q. Okay. Brett, can you please pull up 436-11, defendants?		18 Q. So to give the jury a point of reference, let's say you 19 turn on a hair dryer, how would the velocity of air from the 20 ceiling compare to a typical hair dryer?
16 Okay. And is this the drawing you cited in your 17 report?		21 A. So a hair dryer would classify as high velocity and 22 we've all felt the high velocity of a hair dryer. Here I 23 mentioned it's 25 to 35 feet per minute. A hair dryer would 24 be like 30 times, probably close to a thousand feet per 25 minute as far as a velocity goes, like 30 times stronger
18 A. Yes, it is.		
19 Q. Can you explain to the jury what this shows?		
20 A. Sure. So you see in this drawing at the bottom of the 21 middle is the operating room table in the center of the 22 room. Above that you'll notice the sort of four boxes in 23 the ceiling level, that's representing those supplier vents 24 I just talked about, and you can see here the concentration 25 of where it's over the space above the operating room table.		

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<p>1 blowing air over the patient.</p> <p>2 Q. Well, let's take a look at this is the anesthesia</p> <p>3 machine?</p> <p>4 A. Yes, it is.</p> <p>5 Q. And you can see the operating table here, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And the vents are pointing away from the patient,</p> <p>8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. So those would not be blowing air into the sterile</p> <p>11 field, fair?</p> <p>12 A. I don't know if there's a fan included in there or not</p> <p>13 or whether they're just passive vents.</p> <p>14 Q. Sure, they're not venting heat onto the sterile field,</p> <p>15 how about that?</p> <p>16 A. The vents here are the in the opposite direction of the</p> <p>17 surgical table.</p> <p>18 Q. And you know from your experience, that's the way these</p> <p>19 machines are always set up, right? The vents are always</p> <p>20 away from the sterile field, right?</p> <p>21 A. No, I am not familiar with that.</p> <p>22 Q. You don't know one way or the other?</p> <p>23 A. No.</p> <p>24 Q. Okay. And there was a computer screen, and obviously</p> <p>25 the computer, you have to be able to be around the patient</p>	1639	<p>1 measuring cord or stick and see how high it was?</p> <p>2 A. No, we did an eyeball measurement.</p> <p>3 Q. Eyeball measurement, okay. And then from your eyeball</p> <p>4 and approximations, that's how you made this?</p> <p>5 A. I did not make this schematic.</p> <p>6 Q. Do you know who did?</p> <p>7 A. No, I do not.</p> <p>8 Q. So you're relying on it but you didn't make it and you</p> <p>9 didn't know who made it?</p> <p>10 A. No.</p> <p>11 Q. Do you have any idea of how accurate it is?</p> <p>12 A. I believe it's a fairly accurate representation of the</p> <p>13 operating room, from a schematic sense.</p> <p>14 Q. Just based on your blind trust of somebody you don't</p> <p>15 know?</p> <p>16 MR. GOSS: Objection, Your Honor.</p> <p>17 THE COURT: Sustained.</p> <p>18 BY MR. FARRAR:</p> <p>19 Q. You talked a bit about laminar flow or unidirectional</p> <p>20 flow, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And I think you said it's not a protective field or</p> <p>23 doesn't make a protective field or something like that; is</p> <p>24 that right?</p> <p>25 A. The question was asked whether I determine it to be a</p>	1641
<p>1 and see the computer so it's -- the screen is facing the</p> <p>2 team, correct?</p> <p>3 A. Yes, it is.</p> <p>4 Q. So the vents, whether or not they're active or passive,</p> <p>5 are on the back side of the computer, correct?</p> <p>6 A. On the -- on this monitor they're on the back side, yes.</p> <p>7 Q. So they're also not blowing air into the sterile field</p> <p>8 or venting air in the sterile field, correct?</p> <p>9 A. If they are venting air, it is the back of the monitor.</p> <p>10 Q. What is that blue thing?</p> <p>11 A. I believe you pointed to the Bair Hugger unit</p> <p>12 representation.</p> <p>13 Q. That's not the Bair Hugger that was used for</p> <p>14 Mr. Gareis's operation though, right?</p> <p>15 A. This is a schematic, and I believe it looks like a</p> <p>16 different model.</p> <p>17 Q. I'm just color and looking at the size, that's clearly</p> <p>18 not the 505 Bair Hugger, right?</p> <p>19 A. Correct.</p> <p>20 Q. You didn't measure how high this diffuser -- or I'm</p> <p>21 sorry, this return grille was, correct?</p> <p>22 A. Yes, we did.</p> <p>23 Q. You did? Testify --</p> <p>24 A. We did an approximation measurement.</p> <p>25 Q. At the hospital in the operating room, you didn't take a</p>	1639	<p>1 force field, and I said no.</p> <p>2 Q. Would you look at your December 6, 2017, report. I'm</p> <p>3 sorry, that's the wrong report. The June 2, 2017, report.</p> <p>4 Page 23, subpart D is where I'm looking specifically. Do</p> <p>5 you say in D, the laminar flow characteristic in an</p> <p>6 operating room is an important design feature to provide a</p> <p>7 protective field from infiltration of possible</p> <p>8 contamination. You agree with that, correct?</p> <p>9 A. Yes.</p> <p>10 Q. All right. So it's a protective field, just take issue</p> <p>11 with force field?</p> <p>12 THE COURT REPORTER: I'm sorry?</p> <p>13 BY MR. FARRAR:</p> <p>14 Q. You're okay with protective field, you just take issue</p> <p>15 with force field?</p> <p>16 A. I think it's applied in different context, yes.</p> <p>17 Q. Okay. Talk to you a little bit your inspection of the</p> <p>18 OR. ASHRAE requires two banks of filters for the air coming</p> <p>19 into the OR, correct?</p> <p>20 A. Yes.</p> <p>21 Q. And you know that in OR No. 4 they actually had three</p> <p>22 banks of filters, correct?</p> <p>23 A. Correct.</p> <p>24 Q. So it went above and beyond ASHRAE standards, correct?</p> <p>25 A. There was an additional filter bank, yes.</p>	1641

	1642		1644
<p>1 Q. And in fact, that additional filter bank was HEPA</p> <p>2 filtration, correct?</p> <p>3 A. Yes, it was.</p> <p>4 Q. Which is basically the highest level of filtration we</p> <p>5 can get, right?</p> <p>6 A. It is one of the better ones, yes.</p> <p>7 Q. And in fact, it stops 99.97 percent of any particles</p> <p>8 .3 microns and larger. You know that, right?</p> <p>9 A. Yes.</p> <p>10 Q. It also had a UV light between the two --- first two</p> <p>11 filters, correct?</p> <p>12 A. I was told it had a UV light. I'm not sure where it was</p> <p>13 located.</p> <p>14 Q. Okay. And you don't have any reason to believe it</p> <p>15 didn't have a UV light?</p> <p>16 A. No, I do not.</p> <p>17 Q. That is also not something that's required by ASHRAE,</p> <p>18 correct?</p> <p>19 A. That's correct.</p> <p>20 Q. So above and beyond making sure that the air coming in</p> <p>21 is sterile, correct?</p> <p>22 A. The UV light was an extra beyond the standard -- extra</p> <p>23 piece beyond the standard requirement.</p> <p>24 Q. It had -- well, did you calculate the number of air</p> <p>25 changes per -- what's the ASHRAE standard is 20 air changes?</p>		<p>1 A. It's was a long time ago, I don't recall, but I did take</p> <p>2 a course and did some basic modelling.</p> <p>3 Q. Undergrad?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. You don't have like a Ph.D. or master's in --</p> <p>6 A. No, I do not.</p> <p>7 Q. Do you know what grid independence is?</p> <p>8 A. Repeat the question.</p> <p>9 Q. Grid independence, do you know what it is?</p> <p>10 A. No, I'm not familiar with that term.</p> <p>11 Q. Do you know what mesh independence is?</p> <p>12 A. No.</p> <p>13 Q. Have you ever used LES?</p> <p>14 A. I have not used LES.</p> <p>15 Q. Have you used RANS, R-A-N-S?</p> <p>16 A. I have not used RANS.</p> <p>17 Q. Do you have any opinion as to the quality between LES</p> <p>18 and RANS?</p> <p>19 A. I don't have an opinion between them.</p> <p>20 Q. Do you know what the Navier-Stokes equation is?</p> <p>21 A. Yes, I do.</p> <p>22 Q. What is it?</p> <p>23 A. It's an equation used in computational fluid dynamics.</p> <p>24 Q. Do you know and can you write it out, do you know what</p> <p>25 it is?</p>	
	1643		1645
<p>1 A. 20 total air changes is the minimum requirement, yes.</p> <p>2 Q. Did you calculate what OR No. 4 had when you were there?</p> <p>3 A. Yes, I did.</p> <p>4 Q. What was it?</p> <p>5 A. I'm sorry, just to correct, I calculated by the design</p> <p>6 drawings --</p> <p>7 Q. Sure.</p> <p>8 A. -- what they designed it to be, and I calculated that to</p> <p>9 be I believe somewhere in the range of 26 to 28 air changes.</p> <p>10 Q. Yeah, I think you said 28. So that's above -- either</p> <p>11 way, above and beyond ASHRAE standards?</p> <p>12 A. It's over the minimum requirement of 20.</p> <p>13 Q. So above and beyond the ASHRAE standards?</p> <p>14 A. Yes.</p> <p>15 Q. Finally, Mr. Keen, I want to talk to you a little bit</p> <p>16 about computational fluid dynamics. You're not an expert in</p> <p>17 that, right?</p> <p>18 A. No, I am not.</p> <p>19 Q. You've never done it?</p> <p>20 A. I have not done it. I'm sorry, I've done some basic CFD</p> <p>21 when I was in school.</p> <p>22 Q. You've never modelled anything using computational fluid</p> <p>23 dynamics?</p> <p>24 A. I have in school, yes.</p> <p>25 Q. What?</p>		<p>1 A. I couldn't do that by memory, no.</p> <p>2 Q. Can you solve it?</p> <p>3 A. I think we used it in school. Again, I couldn't do that</p> <p>4 today.</p> <p>5 Q. Do you know what Elghobashi map is?</p> <p>6 A. Sorry, can you repeat the question?</p> <p>7 Q. Do you know what the Elghobashi map is?</p> <p>8 A. No, I'm not familiar with the Elghobashi map.</p> <p>9 Q. You understand, don't you, Mr. Keen, that the setup that</p> <p>10 Dr. Elghobashi used for his computational fluid dynamics was</p> <p>11 not intended to mimic Mr. Gareis's operating room No. 4,</p> <p>12 right?</p> <p>13 A. I don't know whether or not that was the intention.</p> <p>14 Q. You read his report, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And you just testified about all kinds of things that</p> <p>17 you disagree with or have complaints with. Do you have an</p> <p>18 understanding, sir, if it was meant to model Mr. Gareis's</p> <p>19 operating room?</p> <p>20 A. No, I don't have that understanding.</p> <p>21 Q. You just don't know one way or the other?</p> <p>22 A. I don't know that it was intended to match that, no.</p> <p>23 Q. Okay. So maybe that's the confusion then, Mr. Keen,</p> <p>24 maybe you think it's supposed to model it and it's actually</p> <p>25 not and that would take care of your criticisms, right?</p>	

	1710		1712
1 that you did?		1 Q. And the opinion that you've expressed, again, you hold	
2 A. That is correct.		2 that opinion to a reasonable degree of scientific certainty?	
3 Q. And that's what's available on YouTube?		3 A. Yes.	
4 A. That is correct.		4 Q. So let's talk more specifically about the work you've	
5 Q. Would you tell the ladies and gentlemen of the jury what		5 done, then, in this case. Would you tell the ladies and	
6 exactly that video is referring to?		6 gentlemen of the jury what work have you done?	
7 A. So that video refers to a calculation of airflow in		7 A. I think I mentioned this earlier, I did a lot of reading	
8 what's called a modelled operating room, so it was an		8 about what is known about operating room airflow and what	
9 operating room with specific dimensions. There was a Bair		9 other people have done to study whether or not these types	
10 Hugger device in it. There was ventilation flow coming		10 of devices can influence airflow, so I've read a lot of	
11 downwards from the ceiling. There were no moving surgeons		11 independent research. In addition, I carried out my own	
12 or patient. There were no other equipment that would cause		12 research and project, and that involved two things. It	
13 any air motion or heat, so it was a very specific		13 involved my own calculations and it also involved my own	
14 calculation of airflow. And that video was intended to show		14 experiments.	
15 the patterns of airflow in that operating room, that		15 Q. So you read a lot of scientific literature?	
16 modelled operating room.		16 A. Yes.	
17 Q. So that modelled operating room that's based upon the		17 Q. Did you prepare your own model CFD?	
18 airflows from your calculations?		18 A. Yes, I did.	
19 A. Correct.		19 Q. Did you conduct something called an airflow	
20 Q. Now, do you recall what it is that Dr. Elghobashi took		20 visualization experiment?	
21 away from your video on YouTube?		21 A. Yes, I did.	
22 A. I believe he took the dimensions of the room, so the		22 Q. Briefly, can you tell the ladies and gentlemen of the	
23 height, width, and depth.		23 jury what is that? What's an airflow visualization	
24 Q. So your video, your YouTube video, based upon your CFD,		24 experiment?	
25 does it or does it not purport to represent the dimensions		25 A. Well, it's a real world experiment. So it's making an	
	1711		1713
1 of OR No. 4 that the jurors have heard a lot about?		1 experiment -- the visualization means you're going to	
2 A. It does not.		2 visualize how the air flows in the operating room, so a	
3 Q. And OR No. 4 is the operating room that we've been		3 visualization experiment helps you track the airflow	
4 discussing in this courtroom that relates to Mr. Gareis's		4 patterns that are occurring that you otherwise wouldn't be	
5 surgery?		5 able to see with your eyes. So that visualization	
6 A. That is correct.		6 experiment was an experiment to capture what happens in the	
7 Q. Was your CFD model, and we'll see it after a while, but		7 real world.	
8 was it at all intended to capture the reality of		8 Q. So did you also review the expert reports of other	
9 Mr. Gareis's surgery?		9 experts for the plaintiffs in the case?	
10 A. It was not.		10 A. Yes, I did.	
11 Q. Was it designed to measure all of the forces that would		11 Q. Have you reviewed the CFD videos and reports of	
12 affect air movement in the operating room on November 9,		12 Dr. Elghobashi?	
13 2010, at the time of Mr. Gareis's surgery?		13 A. Yes, I have.	
14 A. No.		14 Q. Do you know whether or not Dr. Elghobashi reviewed your	
15 Q. Do you have an opinion, then, to a reasonable degree of		15 report?	
16 engineering scientific certainty as to whether		16 A. He did not.	
17 Mr. Elghobashi's use of the dimensions of the operating room		17 Q. Have you formed any opinions about the Bair Hugger and	
18 used in your video, your model, are sufficient to make		18 its effect on operating room airflow based on the work	
19 conclusions about Mr. Gareis's operating room in this case?		19 you've done in this case?	
20 A. I mean, frankly, neither of the calculations correspond		20 A. Yes, I have.	
21 to the operating room No. 4. They were both corresponded to		21 Q. And do you hold those opinions to a reasonable degree of	
22 an entirely different operating room.		22 scientific certainty?	
23 Q. And so if you had to answer the question does it		23 A. Yes.	
24 correspond yes or no, what does would say?		24 Q. Now, tell us, what's your opinion?	
25 A. It does not correspond.		25 A. My opinion is the Bair Hugger device does not disrupt	

1714

1716

1 the downward airflow from the ceiling in an operating room.
 2 Q. Can you tell us what you base that opinion on?
 3 A. I base it on my own experiments in an actual operating
 4 room with moving physicians and a patient. I base that on
 5 my review of the literature and what other people have done
 6 and on my own calculations.
 7 Q. Now, I heard you say that you performed your own airflow
 8 calculations. Would you tell the ladies and gentlemen what
 9 that means?
 10 A. You've heard -- we've heard a lot about CFD calculations
 11 and how they're done. Basically, if you want to calculate
 12 the airflow, let's say in this room, you set up what's
 13 called a grid, which are a bunch of points in the computer
 14 world, not in fiscal objects but a bunch of points in the
 15 computer world, and you calculate the airflow at each point.
 16 And what that means is you calculate the velocity and the
 17 air pressure at every single point. And so if you calculate
 18 enough points of velocity and pressure, you can stitch all
 19 that stuff together like a puzzle, you put a puzzle together
 20 and it tells the whole picture, so it's calculating airflow
 21 at millions and millions of locations in a space.
 22 Q. So there are things, then, that the CFD can tell us and
 23 things the CFD can't tell us?
 24 A. Correct.
 25 Q. In the context of the work you've done on this case, can

1 operation?
 2 A. No.
 3 Q. Now, in your opinion, what might be useful about a CFD
 4 in this case?
 5 A. Here's the thing about these fluid flow calculations and
 6 the thing people have to keep in mind. They are -- the
 7 phrase we use in our field is they're never right but
 8 they're sometimes useful. They're useful to answer very,
 9 very specific questions.
 10 Okay. So why did I do a CFD calculation? I'll
 11 tell you why. I wanted to answer a very specific question.
 12 My calculation was intended to answer this question. If I
 13 remove everything from the operating room, no heaters, no
 14 anesthesia machine, no surgeons, no moving surgeons, no
 15 opening doors, remove all that, and just let's see if the
 16 Bair Hugger air can interrupt and disrupt the ceiling
 17 ventilation downward airflow, a CFD can answer that because
 18 I've removed everything else.
 19 Q. Well, what answer did you get to that?
 20 A. The answer that I got was the Bair Hugger itself cannot
 21 interrupt the downward airflow from the vents.
 22 Q. So what is it that would make you do a CFD, a form of a
 23 simulation, where you take practically everything out of the
 24 operating room except the Bair Hugger, why would do you it
 25 that way?

1715

1717

1 a CFD tell us how the air moved in the operating room during
 2 the surgery of Mr. Gareis eight years ago on November 9,
 3 2010, precisely between the times of 12:11 p.m. and 2:55
 4 p.m.?
 5 A. These CFD calculations cannot tell you that.
 6 Q. And why not?
 7 A. These calculations only tell you how the flow behaves
 8 depending on your input. So they can only account for the
 9 inputs that you put into the model. So if you wanted to
 10 know and you wanted to calculate the airflow in this OR, you
 11 would have to know where people stood, how they moved, you
 12 would have to know what equipment was there, where was the
 13 equipment and you have to track all of that stuff for the
 14 entire surgery. And no one that I know of has that
 15 information or could do a calculation with all of that
 16 information. You'd have to know, for example, did the doors
 17 open, if they opened when, did someone walk through, and
 18 that kind of information can't be put into a CFD
 19 calculation.
 20 Q. And we'll talk about that more in just a moment, but
 21 you're saying you essentially have to know and have all
 22 these data points from moment to moment for that entire time
 23 period?
 24 A. The entire operation.
 25 Q. And have you seen any data for any part of the

1 A. Simple. Because the Bair Hugger's motion, the air
 2 motion from the Bair Hugger, is dominated by other things.
 3 A door open, a surgeon moves, those things are more
 4 important. If the Bair Hugger by itself isn't going to
 5 disrupt the downward airflow, then it's going to be less
 6 important when you add all of those other things, and so I
 7 was looking at a worse case scenario.
 8 Q. So you were telling us a bit about a CFD model being no
 9 better than the inputs that go into it. Can you give us
 10 some examples of inputs?
 11 A. Yes, I can. So, for the question that I wanted to
 12 answer, that very specific question, I needed to know things
 13 like the dimensions of the room, where the operating table
 14 was, I needed to know information about how the flow went
 15 from the ceiling into the room, so that would be the inputs.
 16 I needed to know how the Bair Hugger air emerged from the
 17 blanket into the room, and I also needed to know some
 18 information about how the air left the room, and that would
 19 be the exit vents. So for my calculation, those were the
 20 critical things I needed.
 21 Q. So does it make any difference whether the exit vents
 22 are powered or not?
 23 A. Yes, it does.
 24 Q. And it may be obvious, but how come?
 25 A. Well, powered vents have suction, there's a fan sucking

11 BEFORE THE HONORABLE JOAN N. ERICKSEN
UNITED STATES DISTRICT COURT JUDGE

(JURY TRIAL - VOLUME X)

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1791

1 P R O C E E D I N G S
2 (9:07 a.m.)
3 THE COURT: Good morning. Welcome back,
4 everybody. And please be seated.
5 And Dr. Abraham, you can resume the witness stand.
6 Good morning. And you're still under oath from three days
7 ago, last week.
8 THE WITNESS: Thank you.
9 THE COURT: Mr. Assaad.
10 MR. ASSAAD: Thank you, Your Honor. May I
11 approach the witness?
12 THE COURT: You may proceed. Yes.
13 CROSS EXAMINATION
14 BY MR. ASSAAD:
15 Q. Good morning, Dr. Abraham.
16 A. Good morning.
17 Q. Did you have a nice long weekend?
18 A. I did. A little too much sun, biking with my kids, butt
19 yeah, yeah, nice weekend.
20 Q. I think it's I think it's one of the first time that I
21 thought it was hotter in Minnesota than it was in Houston.
22 And I don't think I introduced myself to the jury
23 last week. My name is Gabriel Assaad, and I represent
24 Mr. and Mrs. Gareis.
25 Dr. Abraham, you agree with me that air can't pass

Waco, TX 76705 1790

1

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Proceedings recorded by mechanical stenography; transcript produced by computer.

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1 through the hospital drapes, the sterile drapes that are
2 used during on orthopedic surgery, correct?
3 **A.** I've seen no evidence or I've heard no claim that they
4 could, so I agree with you.
5 **Q.** Okay. And you've actually seen pictures of an operating
6 room and how the draping occurs, correct?
7 **A.** Yes.
8 **Q.** And I'd like to go to -- I just want to run through the
9 setup so it will help us answer, like, when we go further
10 on, about a couple questions I have later on. If we could
11

M.B. BLACKWELL : 1615

M R ASSAAD: I'm sorry, correct

14 BY MR ASSAAD:

15 Q. 1615. Now, Doctor, you were here for Dr. Presnal's
16 testimony by deposition, correct, the orthopedic surgeon in
17 this case?

18 A. Was that on Friday?

19 Q. I believe you were here most of the week last week,
20 correct?

21 A. I was here a good portion. I don't know if it was most
22 of but a good portion.

23 Q. And you were here for the testimony of Dr. Presnal, the
24 orthopedic surgeon, that he described how Mr. Gareis was
25 draped during the surgery?

1849

1 **Q.** "And you're running the streamline for 60 seconds in
 2 that individual frame, correct?" And, "That is correct.
 3 I'm tracking the path of the flow over a 60-second time
 4 period in that frame." Correct?

5 **A.** Correct.

6 **Q.** Okay. So just so the ladies and gentlemen of the jury
 7 understand, you run the simulation, say, for the 505, for
 8 5.07 seconds, correct, and you get a file?

9 **A.** Well, I mean that's partially correct. You get -- what
 10 I did, and I testified to this in my deposition, I ran and I
 11 think I ran a RANS study to get the initial guess of the
 12 solution, the initial solution.

13 **Q.** You used RANS?

14 **A.** Yes, I did. And then what I began to do is to take
 15 frames, like frames in a movie, and I think I took up to
 16 3630 frames.

17 **Q.** Is that TRN files?

18 **A.** The frames are from the TRN files.

19 **Q.** Are they separate TRN files or it's off one TRN file?

20 **A.** Separate.

21 **Q.** So you're saying that you had 3,630 different TRN files?

22 **A.** Well, I testified to this in my deposition.

23 **Q.** I understand what you testified in your deposition, but
 24 I'm saying today, you had 3,630 TRN files?

25 **A.** Yes.

1850

1 **Q.** And you deleted most of them?

2 **A.** No, no, no. On page 250, I tell you, you ask, "Now, you
 3 provided TR" --

4 MR. ASSAAD: Wait. He can't read off the
 5 deposition, Your Honor. If he wants --

6 THE COURT: Didn't you ask him to?

7 MR. ASSAAD: No, I did not.

8 THE COURT: All right. Give him a question.

9 BY MR. ASSAAD:

10 **Q.** You had 3,630 TRN files. That's your testimony today?

11 **A.** My testimony is that I had up to 3,630. That is my
 12 testimony today.

13 **Q.** And you produced only one to the plaintiff, correct?

14 **A.** I disagree. I said it on page 250.

15 **Q.** We'll move on. We'll get to the deletion part in a
 16 little bit.

17 You agree that time does not stand still, correct?

18 **A.** I agree time does not stand still.

19 **Q.** And when you create streamlines from a single time
 20 frame, all the streamlines were based on a frozen frame;
 21 correct?

22 **A.** I agree with you.

23 **Q.** Okay. Now, now, real quick, and I don't want -- you
 24 said I mislead the jury. When you turn on the Bair Hugger,
 25 it doesn't get to 43 degrees right away, correct?

1852

1 **A.** That is correct.

2 **Q.** Actually, to get the blanket to 43 degrees, it probably
 3 takes five or six minutes, maybe even up to ten, correct?

4 **A.** I don't know how long it takes, but the heating up of
 5 the Bair Hugger is not related to how I did my calculation,
 6 but I don't know how long it takes.

7 **Q.** But it takes a few minutes, correct?

8 **A.** It may take a few minutes.

9 **Q.** And you've seen studies where just even to get up to
 10 36 degrees when you turn the Bair Hugger on, it's about 3.2
 11 minutes for the blanket?

12 **A.** I don't recall seeing any studies.

13 **Q.** Did you see any internal studies by 3M?

14 **A.** Yes. I saw what I characterize as a tech data sheet,
 15 but I don't recall the studies on the time it takes the Bair
 16 Hugger to warm up. It wouldn't have mattered to me because
 17 I assumed the Bair Hugger was operating at full heat.

18 **Q.** Okay. Now, you said you ran a RANS model to get the
 19 initial conditions for your CFD analysis, correct?

20 **A.** That's what I recall.

21 **Q.** You did not produce that RANS file to the plaintiffs,
 22 correct?

23 **A.** I did not.

24 **Q.** You never compared the Bair Hugger off to the Bair
 25 Hugger on, correct?

	1853		1855
1	Q. And actually it says JP Abraham up here, correct?	1	"Question: Have you ever received an error
2	A. Yes, it does.	2	message in any of the work you did on ANSIS?
3	Q. And it has the date 2017.	3	"Answer: I almost always receive error
4	A. Yes, it does.	4	messages."
5	Q. And that's December 22, 2017, correct?	5	Did I read that correctly?
6	A. Correct.	6	A. Yes, and the next --
7	Q. Now, if you turn to page --	7	Q. Let's go to exhibit -- let's go to Exhibit 463.
8	THE COURT: We'll take a morning recess.	8	MR. BLACKWELL: Your Honor, may the witness
9	15 minutes.	9	please finish his answer?
10	(Recess.)	10	THE COURT: Next question.
11		11	BY MR. ASSAAD:
12		12	Q. Exhibit 463, and you were looking at Exhibit 463 which
13		13	is a result file that you produced to the plaintiff
14		14	regarding your CFD analysis on the model 505, correct?
15		15	A. Yes.
16		16	Q. And if you turn to page 10 of Exhibit 463, you see an
17		17	error message has occurred in the subroutine interaction,
18		18	correct?
19		19	A. It's actually a warning message, but there is a message
20		20	the computer is giving in that subroutine.
21		21	Q. It actually says error, correct?
22		22	A. It does, but at the end it says warning, and it gives
23		23	the warning.
24		24	Q. And if you go to page 13 of the same exhibit, there is
25		25	another error message, correct?
	1854		1856
1	11:10 A.M.	1	A. It is the same warning message that's given.
2		2	Q. Now, we can take down that exhibit.
3	(In open court with the Jury present.)	3	Now, I asked you this before, but you agree with
4	THE COURT: Be seated. You may proceed.	4	me that you for each of the 505 and 705 models, you can
5	MR. ASSAAD: Thank you, Your Honor.	5	only provide me with one result file, correct?
6	BY MR. ASSAAD:	6	A. I disagree.
7	Q. Where we left off we were discussing about error	7	Q. Let's go to page 234 of your deposition that was taken
8	messages that CFX produces or can produce while you run	8	in July of 2017.
9	your CFD code, correct? Do you recall that?	9	A. Is your question by a certain date, or is your question
10	A. Correct.	10	just overall how many results files?
11	Q. Okay. And you've actually received error messages in	11	MR. ASSAAD: Your Honor, I would like to admit
12	the CFD model you did for the 505, correct?	12	Exhibit 463 in evidence, which is his result file that he
13	A. Yes.	13	produced.
14	Q. And in fact you almost always receive error messages	14	MR. BLACKWELL: Objection, Your Honor.
15	when you do CFD modeling, correct?	15	Relevance.
16	A. Well, it's very common that you'll receive error	16	MR. ASSAAD: It's the result file of his own CFD
17	message or guidance messages from the software. It's very	17	analysis.
18	common. I don't know if it's almost always, but very	18	THE COURT: I'll reserve ruling. The offer comes
19	common.	19	out of the blue disconnected from any foundational
20	Q. Let's turn to your deposition on March 15th, 2018, page	20	questions to the witness, so I will withhold ruling on
21	152.	21	that.
22	A. March 15th?	22	BY MR. ASSAAD:
23	Q. Yes. February 15th. I'm sorry. 2018.	23	Q. Let's go to Exhibit 463 again, sir. What is
24	A. Could you give me the page number again?	24	Exhibit 463?
25	Q. 152.	25	A. Exhibit 463 is called a log file.

	1857		1859
1	Q. And a log file is the results of a, of a time stamp,	1	"Answer: Yes."
2	correct?	2	Did I read that correctly?
3	A. No.	3	A. You read that correctly.
4	Q. What is the log file?	4	Q. And you essentially went and deleted any unimportant or
5	A. The log file gives you details about a calculation.	5	unessential files that you believed were unimportant or
6	Q. So it gives you details about a calculation. This was	6	unessential, correct?
7	created in your CFD analysis of the 505, correct?	7	A. I deleted things that were contained within the master
8	A. I believe so.	8	file and weren't needed.
9	Q. And this was done in -- this is routinely created in	9	Q. So you deleted files that you believed were not needed,
10	the -- in any type of CFD analysis, correct?	10	correct?
11	A. I wouldn't say any type of CFD analysis, no.	11	A. Correct.
12	Q. Well, it's created as a result of a CFX program in	12	Q. Now, with respect to the geometry that you used in your
13	performing your calculations on the model operating room	13	CFD model for both the 1.2 second model, the 750, and the
14	performed in this case, correct?	14	507 second model, the 505, that geometry you did not
15	A. Okay. Could you just ask that question again?	15	create, correct?
16	Q. This was created in response to your modeling of the	16	A. That is correct.
17	CFD -- of your CFD modeling of the operating room in your	17	Q. You obtained that from 3M, correct?
18	505 analysis, correct?	18	A. Correct.
19	A. Correct.	19	Q. Now the animation that you put up in, the video
20	Q. And you have seen this document before, correct?	20	animation that you showed to the jury, those were
21	A. I don't know if I've seen this exact document. I've	21	streamlines, correct?
22	seen documents like this.	22	A. Yes.
23	Q. You have no -- you agree that -- you've never seen this	23	Q. And you agree with me that particles do not follow the
24	document before?	24	path of streamlines, correct?
25	A. There has been a lot of -- I probably have. There has	25	A. I would agree. Particles do not necessarily follow the
	1858		1860
1	just been so many documents that, I mean I'm assuming I	1	path of the streamlines. Streamlines are the airflow
2	have.	2	lines, and particles tend to fall out of the air, which is
3	Q. This was created off your computer, correct?	3	why we have to dust frequently. Those are particles that
4	A. Yes. I can see, I can see that at the top, yes. I	4	land on surfaces, and that's an example of particles not
5	created this document.	5	following the airflow.
6	Q. And you saw this at your depo, and it's marked Exhibit	6	Q. And you agree with me that you did not add any
7	Number 16, correct?	7	particles to your CFD analysis, correct?
8	A. Yes.	8	A. Well, no. I disagree. In my deposition I made this
9	Q. So your computer created this result file?	9	clear. I added particles that were air particles, so they
10	A. Yes.	10	were neutrally buoyant. I stated it in my deposition.
11	Q. And you agree with me that if your computer created it,	11	They were air particles, and I followed those.
12	it's an authentic copy of the results of your CFD 505 or	12	Q. Can you go to page 176 of the July 2017 deposition,
13	your logs of the 505 analysis, correct?	13	line 24.
14	A. It is a, it is the log of the 505.	14	"Question: So you agree with me you didn't add
15	MR. ASSAAD: Your Honor, I offer Exhibit 463 into	15	particles to the flow, correct?
16	evidence.	16	"Answer: I did not."
17	MR. BLACKWELL: No objection, Your Honor.	17	Did I read that correctly?
18	THE COURT: 463 is received.	18	A. You read it correctly, but the context you're missing.
19	BY MR. ASSAAD:	19	Q. Do you agree with me that in your CFD operating room
20	Q. Let's go back to where I left off regarding the files	20	you didn't even have the Bair Hugger blower in your model?
21	that were produced to the plaintiff. If you go to page 234	21	A. Can you explain what you mean by that?
22	of the deposition of July of 2017, line 16.	22	Q. The blower, this thing, that sucks air in, you did not
23	A. I'm not quite there yet. I'm there.	23	have that in your model, correct?
24	Q. "Question: I only have one PRN file. You understand	24	A. I did not include that structure.
25	that, correct?	25	Q. And you'll agree with me that a Bair Hugger that sits

	1861		1863
<p>1 on the floor is going to affect the flow around the 2 operating room table?</p> <p>3 A. I think everything would have some effect on the flow.</p> <p>4 Q. My question, listen to my question. It's about the 5 Bair Hugger. You agree with me that a Bair Hugger that 6 sucks 30 CFN, cubic feet of air, off the floor is going to 7 affect the airflow around the operating room table. You 8 agree?</p> <p>9 A. I agree everything would affect the airflow.</p> <p>10 Q. You didn't model any doors opening or closing in the 11 operating room, correct?</p> <p>12 A. I did not.</p> <p>13 Q. You didn't model any people moving in the operating 14 room, correct?</p> <p>15 A. Correct.</p> <p>16 Q. You didn't put any other tables, like back tables where 17 the surgical instruments and the implant sit in the sterile 18 field, in your model, correct?</p> <p>19 THE COURT: Five more minutes, Mr. Assaad.</p> <p>20 MR. ASSAAD: Excuse me?</p> <p>21 THE COURT: You have five more minutes.</p> <p>22 THE WITNESS: That is incorrect.</p> <p>23 BY MR. ASSAAD:</p> <p>24 Q. You had no air going over the arms of the patient in 25 your model, correct?</p>	1861	<p>1 expert in the field. In fact, that's what I do, and that's 2 what my colleagues who are editors do. So I agree that 3 that may be the instructions for general papers, but I 4 don't -- I think it's the editor's prerogative.</p> <p>5 Q. You understand that according to the publisher that the 6 editor is going to assess the suitability for the 7 publication of the paper, but it will then be double blind 8 peer reviewed by expert referees. Isn't that what the Heat 9 Transfer Journal states?</p> <p>10 A. It may or may not.</p> <p>11 Q. Why don't you turn to page 456? Doesn't it state on 12 the bottom paragraph under peer review that it is to be 13 double blind?</p> <p>14 A. You did read it correctly. What it states is, Once 15 your paper has been assessed for suitability by the editor, 16 it will then be double blind peer reviewed by expert 17 referees, and it's my experience and practice that if the 18 editor is an expert in that area, they often handle the 19 review themselves.</p> <p>20 Q. What is required, what is stated here in the journal is 21 not what occurred with your paper that was published in, by 22 Dr. Minkowycz, the editor in chief, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And in fact, you communicated with Dr. Minkowycz about 25 your paper before you submitted it, correct?</p>	1863
<p>1 A. That is correct. I had the air exit by the patient's 2 head and neck.</p> <p>3 Q. And you agree with me that if there was a heat source 4 that you believed would affect your model that that would 5 need to be included in the model, correct?</p> <p>6 A. I agree if there is a heat source that affects the 7 specific question I'm trying to answer, and I talked about 8 that last week, then, yes, I would need to include it.</p> <p>9 Q. And you didn't include a bovie, anesthesia machine or 10 personal computers in your model, correct?</p> <p>11 A. I did not include -- well, I would say this: I did not 12 include the heat from any of those devices.</p> <p>13 Q. Now, you talked about your publication being peer 14 reviewed, correct, on Friday, correct?</p> <p>15 A. Yes.</p> <p>16 Q. You agree with me that a double blind review is where 17 the author and the reviewers do not know who each other 18 are?</p> <p>19 A. I agree.</p> <p>20 Q. And you agree with me that according to the 21 instructions of Numerical Heat Transfer where your paper 22 was published that it requires a double blind review?</p> <p>23 A. No. I think that's probably the instructions, but I 24 believe, and it's my practice, the editor has the 25 opportunity to handle the review themselves if they are an</p>	1862	<p>1 A. That is correct.</p> <p>2 Q. Now, let's go into the -- you discussed about that 3 video we saw yesterday about the person walking through the 4 doorway, the Sarinen paper?</p> <p>5 A. I recall that.</p> <p>6 Q. You understand that that was an isolation room test, 7 correct?</p> <p>8 A. Well, I think it was a positive pressure isolation 9 room.</p> <p>10 Q. Do you believe there was ventilation in that study?</p> <p>11 A. I would have to review the paper to see the 12 ventilation.</p> <p>13 Q. Let's go to Exhibit 464, and because I only have a 14 couple minutes --</p> <p>15 THE COURT: That's based on your two hours. If 16 you need more, let me know.</p> <p>17 BY MR. ASSAAD:</p> <p>18 Q. Are you at Exhibit 464, sir?</p> <p>19 A. Yes, I am.</p> <p>20 Q. Go to page 3, top paragraph, and you reviewed this 21 study before, correct?</p> <p>22 A. Yes.</p> <p>23 Q. You agree with me that the test case was a scenario 24 without ventilation?</p> <p>25 A. Just let me review this to make sure. Yes.</p>	1864